EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO CASE CONSOLIDATION:	
Terreski Mullins, et al., vs. Ethicon, Inc., et al.	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Case No. 2:12-CV-02952	

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OCTOBER 5, 2015

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Deposition of PROF. DR. MED. UWE KLINGE, held at The Quellenhoff Hotel, Monheimsallee 52, 52062 Aachen, Germany, commencing at 10:07 a.m., on the above date, before Trina B. Wellslager, Registered Professional Reporter and Notary Public.

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GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.591.5672 fax
deps@golkow.com

APPEARANCES:

ANDERSON LAW OFFICE, LLC
BY: BENJAMIN H. ANDERSON, ESQUIRE
1360 West 9th Street
Cleveland, Ohio 44413
(216) 589-0256
ben@andersonlawoffices.net
Representing Plaintiffs

THOMAS, COMBS & SPANN, PLLC
BY: DAVID B. THOMAS, ESQUIRE
300 Summers Street
Suite 1380 (25301)
Post Office Box 3824
Charleston, West Virginia 25338
(304) 414-1800
dthomas@tcspllc.com
Representing Defendants

ALSO PRESENT:

Raquel LaPointe, Paralegal, Anderson Law Office

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EXHIBITS
(Attached to Transcript)
(Exhibit No. 6 was retained by Mr. Thomas)

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PROF. DR. MED. UWE KLINGE, called as a witness by the Defendants, having been first duly sworn, testified as follows:

THE WITNESS: I swear.

MR. ANDERSON: Okay. I have a stipulation here. We understand the court reporter is not authorized to administer oaths in this venue. Nevertheless, we request that she administer the oath and we stipulate that we waive any objection to the validity of the deposition based on the oaths. Thanks.

So stipulated.

MR. THOMAS: Agreed.

MR. ANDERSON: Okay. That sounds good. Now I'll just put just a quick thing on the record that we have agreed, and Dave you can correct me if I'm wrong about any of this, but we have agreed that this deposition will be strictly limited to matters that have occurred in 2014 and 2015 to date.

We objected to this deposition because Dr. Klinge has been deposed by Mr. Thomas and other defense counsel in the Ethicon case for 14 hours in the gross litigation, some of that related to pelvic organ prolapse, much of it was related to general topics that he has had opinions on, and those

opinions have stayed the same throughout this litigation in most respects.

And then he was deposed another 14 hours in November, 2012, on TVT matters, also general matters, also fact witness matters. He's been cross-examined for trial purposes on three occasions.

So because there's -- his reports have remained essentially the same throughout these years, and he's been deposed many times, and he's been asked to sit for his deposition and trial, we have asked that this deposition be strictly limited to his writings, his teaching, conferences and things like that that would relate to his CV just for the last two years, and any literature that has become available in the last two years, or since December of 2013. And any questions that could have been asked or were asked at prior depositions, and we are going to object and instruct -- I'll just instruct the witness not to answer. So that's our short thing we need to put on the record.

MR. THOMAS: Thanks, Ben.

MR. ANDERSON: Thank you, Dave.

MR. THOMAS: I agree with it in spirit and substance. The last deposition, as you're aware,

where we discussed the TVT device was November, 2013. It's my goal not to cover ground that we did cover or could have covered back at that time. There will be times that I have to refer back to prior testimony as context or as predicate. I'm sure that won't be a problem. I hope that won't be a problem.

But it's not my goal to do more than is required to understand the contents of his report in the Mullins' case, as well as any changes in Dr. Klinge's personal circumstances, his work or literature generally since that time.

MR. ANDERSON: We will see how we go, and if we start referring to a bunch of old testimony, I'm going to object and tell him not to answer. And if we start going into a report that is basically the exact same report that you've had for the last four years I'll object and tell him not to answer, but let's see how we get.

MR. THOMAS: I bet you we do just fine.

DIRECT EXAMINATION

BY MR. THOMAS:

Q. Good morning, Dr. Klinge.

A. Good morning.

Q. How are you this morning?

A. Quite well.

Q. Good.

(Klinge Exhibit No. 1 was marked for identification.)

Q. Let me show you what I've marked as Deposition Exhibit No. 1. Deposition Exhibit No. 1 is the report that has been filed in the Mullins' case bearing your name. Fair?

MR. ANDERSON: I think his question is, does it bear your name?

THE WITNESS: Yeah, uh-hum.

MR. ANDERSON: Okay.

Q. And is Exhibit No. 1 the complete report of the opinions you intend to offer in this case?

MR. ANDERSON: Well, objection. It is the report that he intends to offer in this case.

A. I cannot -- shall I control whether all pages are in this attachment or is it complete?

Q. I'll represent to you it's what was produced to me.

A. And you said that it's complete?

Q. Right.

A. Okay. I will trust it.

Q. But are those the complete opinions you're prepared to offer in this case?

A. If this is the one you get from Mr. Anderson, and if it is complete, then I agree.

Q. I'll represent to you I've made every effort to give you exactly what Mr. Anderson gave me. If I didn't, it's my mistake or somebody under me's mistake, or perhaps even Mr. Anderson's mistake, but I think it is complete.

A. I don't expect anything else.

Q. It's been represented, Dr. Klinge, that the opinions that you offer today are the same opinions that you offered in the Lewis case, insofar as it relates to generally the TVT device; is that fair?

MR. ANDERSON: Objection. Go ahead.

A. I don't say or I don't understand what do you mean by same. There are some same principles, there are some same ideas, there are some same findings, similar findings.

Q. Let me ask it this way. I'm sorry.

A. But of course there are some differences in wording or...

MR. ANDERSON: Depending on the questions you ask he's saying there may be differences in wording, but in general I think he's asking you, in general are your opinions the same. Is that fair?

THE WITNESS: Yeah, but it is -- it is

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necessary to define what is in general, what are you relying on?

Q. Let me tell you what I'm trying to avoid, Dr. Klinge. I'm trying to avoid going through your opinions line-by-line in this report, Exhibit 1, which are some 39 pages, to ask you if these are opinions that are new and different from your prior opinions or if they're the same.

Can you tell me today, having prepared Exhibit No. 1 for the Mullins' case, whether you have any opinions that you haven't expressed before?

MR. ANDERSON: Objection. Just one second. As I told counsel in my writings to you when we prepared this report, we tried to prepare the report in a manner that would be consistent with old reports. In fact, we used the old reports and we had to make some updates, of course.

But I will represent to you, as an officer of the court, that his opinions are in general the same opinions he's given you for the last four years with regard to the material science of surgical meshes, specifically as it relates to Ethicon. I don't know what more we can do than that, than to tell you that his opinions are essentially the same as they were before.

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BY MR. THOMAS:

Q. Okay. Dr. Klinge, having prepared Exhibit No. 1, do you recall adding any new opinions that you had not expressed before?

A. We can go through all these points. If you have the impression that it is a different -- that there are differences in regard to the previous ones, then feel free, we can discuss them; whether you have some questions we can discuss it. If you agree to all this, it is up to you to define which of these points you have the impression that it's different than the previous one.

Q. Well, with all due respect, Doctor, you are the one who is giving testimony about your opinions in this case, and all I'm trying to understand is, in your own mind, have you developed any new opinions for this case that you have not expressed before relative to the TVT mesh?

MR. ANDERSON: And I'm just going to object, say that he's tried to answer your question, and I've tried to answer your question, and I thought we made it pretty clear that his opinions in general are the same.

MR. THOMAS: I just --

MR. ANDERSON: No, let me finish, because I

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don't think we need to be arguing on this. You're wasting time. He's given you his opinions. The report is what it is, and it's essentially the same report you've gotten for four years, and what we're here to do is to talk about the things he's done in the last two years.

So are his opinions in general the same? Yes. And you can -- and you can look at that by looking at the summary of opinions.

MR. THOMAS: But, Ben, you're not under oath and you're not going to testify.

MR. ANDERSON: I don't care. I'm an officer of the court and you I have agreed to certain things.

MR. THOMAS: Please.

MR. ANDERSON: And one of the things that you did -- you can get upset if you want, I don't care. But one of the things we did when I agreed to do this deposition was you said, well, does he have any new opinions? And I said, no, you can see from his report it's the same report. In fact, it's even smaller than the TVT than this one because he didn't have an analysis of explants. I told you that weeks and weeks ago.

And you're trying to get him to say, are your opinions exactly the same? That depends on what

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your questions are and that's what he's trying to say. In general his opinions are the same. However, if you have specific questions, he's happy to answer them. I don't know what more we can do for you than that, Dave.

MR. THOMAS: Ben, I'm not upset. I am trying to understand what his opinions are, and I've asked him, and you've just used much more of the transcript than I have so far. Let's just move on and do the best we can here.

BY MR. THOMAS:

Q. Doctor, if you'd turn to the last page of Exhibit No. 1, the very back. Do you see expert reports? Did you review the expert report of Dr. Iakovlev?

A. Yes.

Q. And did you review the expert report of Howard Jordi?

A. Yes.

Q. Now, did you review the expert report of Dr. Jordi in the Mullins' case, which is the case that's here, or was it an expert report from another case, do you know?

A. I'm not sure.

Q. Okay.

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MR. ANDERSON: It's Mullins.
MR. THOMAS: Thank you.
Q. Did you review the expert report of Dr. Jordi in the Mullins' case prior to the finalization of your report in this case?
A. I don't remember.
Q. Is the expert report of Dr. Iakovlev that you reviewed in the Mullins' case?
A. Yes.
Q. Do you know whether you reviewed the expert report of Dr. Iakovlev prior to the finalization of your report, Exhibit No. 1?
A. I don't remember.
Q. There are a number of other expert reports that follow here: Ducheyne, Elliott, Thames, Barbolt, Greenberg, Klosterhalfen and Sexton. To my knowledge those reports at the time you prepared your report were not available at the time that you prepared your report in this case.
MR. ANDERSON: Okay. Let me just -- you said some of these things may be my mistake, so I need to step in.
Ducheyne is something that, as you know, he has prepared expert reports for the last four years in numerous cases. Ducheyne was an old one that should

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have been removed from the reliance list because that was from I have no idea how many years ago.
Shelby Thames would have been one from a long time ago.
Barbolt he reviewed. Greenberg is old. Bern Klosterhalfen, he reviewed it, but that would have been in relation to the TVT -- it's the same one he gave in the Lewis case. Sexton is old.
THE WITNESS: Old.
MR. ANDERSON: So I apologize.
MR. THOMAS: That's okay. I'm just trying to understand what's -- what's in play and what's not.
MR. ANDERSON: Yeah.
BY MR. THOMAS:
Q. Have you reviewed other expert reports of Dr. Iakovlev, other than the Mullins' case?
A. I don't think so.
Q. Okay. Have you reviewed other expert reports of Dr. Jordi, other than in the Mullins' case?
A. I don't think so.
Q. Doctor, you have in front of you a document that bears some handwriting on yours. Is that your copy of your expert report?
A. That is correct.
Q. May I look at it, please? I'm going to mark

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this as Deposition Exhibit No. 2.
MR. ANDERSON: Uh-hum.
Q. And we'll come back to that in a moment. Thank you.
(Klinge Exhibit No. 2 was marked for identification.)
(Klinge Exhibit No. 3 was marked for identification.)
Q. I'm going to hand you what's been marked as Deposition Exhibit No. 3, and represent to you that Deposition Exhibit No. 3 is a copy of your current CV that was supplied to me by counsel last week. Do you have that?
A. Yes.
Q. Is -- the best of your knowledge, is this a current copy of your CV?
A. Yes.
Q. If you go to the page, participation and moderator at other meetings.
A. Yeah.
Q. What are you trying to show here? What does it mean to be a participator and moderator at other meetings?
A. My task mainly in these meetings was giving key lectures, keynotes, making the moderate -- moderation of

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the entire session or demonstrating operations.
Q. Okay. When you say "demonstrating operations," are you actually doing procedures that other people observe?
A. Yes.
Q. I thought that you quit doing surgery in 2006.
A. Yeah.
Q. So a number of these meetings occur after 2006, do you see?
A. Yes. The operation demonstration is -- is related to the Second Hernia Telesurgery Meeting in November, 2000, on behalf of Ethicon, where I was asked to demonstrate operations.
Q. I understand. But then you have a number of meetings, beginning on four, going down through 19.
A. Yeah.
Q. Where you attend various organizations -- various meetings in Aachen.
A. Yes.
Q. And are you demonstrating surgeries in those procedures, in those meetings?
A. Only until 2006.
Q. Okay. And after that time what's your role with those meetings?
A. Giving lectures, moderation, discussing the

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operation that has been transmitted to the audience there, yeah.
Q. And from 21 through 25, these are the master classes that you've given, sponsored by the FEG?
A. From 2000 -- organized by -- which one?
MR. ANDERSON: Twenty-one.
A. The Masterclass in Baden-Baden, they were sponsored by the FEG.
Q. And you're scheduled to do one in 2016 as well, correct?
A. 2016 is next year?
Q. You're scheduled to do that with the FEG?
A. I'm not sure. I don't know. 2015, this year, yes.
Q. Has that not happened yet?
A. No. It's in the beginning of November, 5th, 6th.
Q. Okay. That's the one I've seen. Thank you. I'm sorry.
A. November of this year.
Q. Okay, great. On the page immediately prior to that page on your CV, Entry No. 176, you gave a presentation in Brazil by Skype on October 3l, 2014.
A. Yes.
Q. On How Far From the Ideal Mesh.

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Did you have written materials for that presentation?
MR. ANDERSON: Objection to form.
A. Apart from the PowerPoint presentation that has been transferred to Brazil for this, I don't have any.
Q. Do you still have a copy of the PowerPoint presentation that you used for the presentation in Brazil?
A. I'm sure I can find it.
Q. Okay. 182, there is an entry for ideal meshes of PVDF as the safer alternative to polypropylene.
A. Yes.
Q. Given on June the 12th, 2015, in Paris, France. Tell me about that presentation, please.
A. It was an invitation -- there is a hernia club in France who makes this conference once a year, since several years, and I was invited to give a lecture on PVDF as a possible alternative at this conference.
Q. Does the hernia club have a name?
A. Club Hernie, Charite.
MR. ANDERSON: There you go. Imagine that.
Q. Is it sponsored by any professional organization?
A. It is sponsored by all manufacturers, from Ethicon, as well as Dahlhausen, as well as Covidien, as

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well as BARD. So there has been 10, 15, industrial stands that --
Q. Is the FEG a sponsor of this organization as well?
A. No.
Q. Did you have a PowerPoint presentation for that?
A. I did have, surely, and I'm sure that I can find it.
Q. Okay. And 183 you gave another presentation in Belgium on September the 17th, last month.
A. Yep.
Q. On PVDF?
A. Yeah.
Q. And tell me about that presentation, please.
A. I was asked to -- to give a lecture about PVDF because they -- obviously they felt that they have a leg of information to this, and this was a -- an organization, it was headed by Dr. Belleford and Professor Meterly (phonetic), and it was sponsored by the Belgium distributors of DynaMesh.
Q. Okay.
A. And there has been totally five, six presentations.
Q. At different times over what period?

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A. No, no, no, in this evening.
Q. Okay. And did you have a PowerPoint presentation that you gave at that time?
A. Surely I -- I had, and presented it.
Q. 184, just October the 16th --
A. It's coming next week.
Q. Okay. You haven't given it yet.
A. Not yet.
Q. Okay. Mesh classification. What's that about?
A. Mesh classification. Yeah, I was asked by the -- by the surgeon who organized this regular meeting once a year to give a lecture on mesh classification, as this is an important issue, and she felt that she needs some more information about this. And as we prepared a mesh classification some years ago, I think I was asked to give there a lecture about this topic.
(Klinge Exhibit No. 4 was marked for identification.)
Q. Doctor, I'm going to hand you what's been marked as Deposition Exhibit No. 4, and this is a document we've talked about before. It's a document that you authored with Dr. Klosterhalfen titled, Modified Classification of Surgical Meshes For Hernia Repair Based on the Analyses of a Thousand Explanted Meshes. Is this the mesh classification to which you

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just referred?
MR. ANDERSON: Is this paper part of what he was asking you about at that conference?
A. It is part of, of course. It is a more general lecture because you have several classifications for meshes. It is possible to create some more classifications about the meshes, and it has to be or you have to put it into the context what to say with your classification.
And, of course, one option is this classification, what we published in Hernia, because this is the one who predicts the risk of a material in regard to scarring and inflammation. So, therefore, it's just one part, it's an important classification, but it is -- the lecture is not restricted to just this. It's a more broader overview of what is possible and what is the value of the different classifications.
Q. What other --
A. If you're interested, then you can join.
Q. Okay. Have you prepared your PowerPoint presentation for that meeting yet?
A. Widely.
Q. Widely?
A. Not finally, the final proof is not there, but of course I have prepared it to a good extent.

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Q. Since our last deposition when we discussed TVT, have you given other presentations on the mesh classification system that you have in Exhibit 4?
A. I don't recall that this was the specific topic, mesh classification.
Q. Okay.
A. It should have been there in the titles of the presentations there.
Q. Okay. And just to go back, if you go back on the prior page of your CV, on page or No. 156, it talks about the classifications of meshes for risk assessment. I guess I understood that's where you first presented this new classification. Is that fair?
A. Yeah.
Q. And as I looked through the list I didn't see any other presentations on mesh classification unless --
A. 162.
Q. Okay. That's in German.
A. That's in German. But, however, it's classification of mesh, of meshes.
Q. Thank you. I wouldn't have known that unless you told me. Any others?
A. Sure. I don't see any.
Q. What is the status of the classification that you and Dr. Klosterhalfen proposed for surgical meshes

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for hernia repair that's in Exhibit 4?
MR. ANDERSON: Objection to form. Go ahead.
A. What -- I don't understand what you're thinking of when you say, "What is the status"?
Q. All right. When we talked last time you said that you put this together and presented it to a number of manufacturers with the hope of getting some sort of consensus about a mesh classification system. I'm very broad-brush stating that. That's what I recall of your testimony. Is that fair?
MR. ANDERSON: Objection; misstates prior testimony.
A. If I remember correctly we had some meetings with manufacturers in Munich to discuss these issues to make a standardized or a better characterization of textile meshes. But there hasn't been any ongoing activities in this direction.
Q. Okay. So is it fair to understand that since you had those initial meetings that when you discussed your proposed classification in Exhibit 4, there had been no movement by you or by the industry to adopt this classification?
MR. ANDERSON: Objection; form.
A. First of all, there hasn't been no movement by the industry so far I know.

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Q. Okay.
A. I believe that they adopt this classification because they used it increasingly as argument, and I didn't see any objection to this classification by the industry that they don't agree to it. So, therefore, I think they adopt it.
Q. Have you ever seen anything in writing that suggests to you that any company has adopted the modified classification of surgical meshes for hernia repair that's contained in Exhibit 4?
A. If you mean if I know that any company uses the classification or the measurement of the pore sizes for their products, and I don't know. At least they didn't publish it.
Q. Okay. And for the presentation that you're to give in two weeks, or ten days, what other mesh classification systems will be part of your presentation?
A. If I remember correctly, what I will tell in ten days, is usually a classification is intended to classify meshes for similar properties. This can be a classification according to the price, can be a classification according to the color. It can be a classification for the size, it can be a classification for the indication, it can be a classification for the

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risk of infection. That is somewhat, somehow how Amid intended to provide his classification. It can be a classification to predict the risk of scarring and inflammation. That is a classification we are focusing in.

So there are a lot of possible classifications of meshes, and therefore you have to put it into the context, what are you or what for -- what are you looking for when using a classification, and therefore you have to define the end point. That is -- so there is no general classification of all meshes. That is the message of this.

Q. Is your presentation that you're going to give in ten days focusing on mesh for hernia repair?

A. It is textiles in surgery.

Q. So --

A. It is not limited, but it is not focused on any other part.

Q. Will your presentation that you give in ten days advocate a particular mesh classification system?

A. Advocate in the -- in the meaning that I -- there are hardly any -- any alternatives. So if you want to look at the risk for infection for several devices, it is possible to take the classification of Amid. I don't know any others who's able to or who's

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focusing on the risk for infection.

If you want to predict the risk for scarring and inflammation, you have to stick to our classification based on -- on the pore sizes. There is no alternative, so therefore I -- I will point out that there are several options.

Q. Okay. And when you say our classifications, you're referring to that that's in Exhibit 4?

A. This article in Hernia.

Q. Okay.

MR. THOMAS: Just for the record, Counsel, I noticed when I was going through this that I'm short one page to this exhibit.

MR. ANDERSON: Okay. I'll add to it later.

MR. THOMAS: Okay.

Q. Dr. Klinge, since you and Dr. Klosterhalfen prepared Exhibit 4, have any of the statements that you've expressed in this study changed?

MR. ANDERSON: In this entire study that you're looking at?

MR. THOMAS: That's right.

MR. ANDERSON: Oh.

A. We had the impression that it should be -- that this classification is mainly, but it is -- it is focused on textiles in a tension-free area, flat meshes

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in a tension-free area. This is expressed in the document as I remember already, but maybe it should have been underlined more -- more clearly.

Q. Okay. Any other changes or additions to the Exhibit 4 in your current state of your proposed modified classification of surgical meshes for hernia repair?

A. Nothing that I have the impression that we really need to correct it or to change it. We already addressed all the limitations, we addressed that the -- that it is a proposal and we addressed the scientific basis for this. So I don't see a need to -- to make a substantial correction to this.

Q. Okay. If you'll go to Page 258 of Exhibit 4, please. I'm sorry, the next page. It's the last page of the exhibit. I have it as 258. I'm sorry. The last page -- on the right side, about three-quarters of the way down, there is a statement, "However, it is still open for further studies whether 500 micrometers is a reliable limit for histology and a thousand micrometers for the calculation of the effective porosity or whether this should be modified." Is this still a correct statement today?

MR. ANDERSON: Objection. Go ahead.

A. In the meaning that it is still open for

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further studies, we are still waiting on some other studies providing data that are in conflict with these limits. Yeah, it's still open and we are still waiting.

Q. Okay.

A. We didn't receive any data that are rejecting our hypothesis.

Q. Later on in that paragraph it states, "It may be speculated whether the assumption of a best pore size of 1,000 micrometers for preserving an effective porosity has to be adjusted for; for example, meshes of polyvinylidenfluoride PVDF with its smaller foreign body granuloma do not show bridging of scar throughout the pores even at small pore sizes of less than 650 micrometers, whereas polypropylene monofilaments usually do." Is that still a true statement?

A. Yes.

(Klinge Exhibit No. 5 was marked for identification.)

Q. Dr. Klinge, I'm going to hand you a copy of your Notice of Deposition which I've marked as Deposition Exhibit No. 5. The Notice of Deposition asks you to bring certain things to the deposition. And I'm sure you know this. If you don't, that's okay.

Mr. Anderson and I exchanged communications about what you will and will not bring to the

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deposition, and I don't want to go through each one of them, I just want to know what it is that you're prepared to give me so we can go through that.

MR. ANDERSON: Okay. So what we -- without going through all of it, I think we've addressed each and every one of the 19 plus three subparts, so 22 categories of documents that were asked for. Many of these were taken care of by providing them through the report and the CV.

He -- I indicated to you that he has not billed me yet for the -- for No. 1. When he does, I'm happy to provide that information to you. I did bring you a thumb drive which would be all of the literature that would be for the last two years since his last deposition.

And many of your categories were objectionable, as you know, and I sent you what he was able to quickly grab in terms of PowerPoints for the last two years. You've identified a couple more here today. I'm happy to have him provide those to me so that I can give those to you.

Otherwise, they're either objectionable, already provided previous to this Notice of Deposition, or provided to you since then.

(Klinge Exhibit No. 6 was marked for

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identification.)

Q. Okay. I'm going to mark the thumb drive as Deposition Exhibit No. 6. And, for the record, I'm going to take this with me and provide a copy to counsel. Is that all right with you?

MR. ANDERSON: Sure. No, that's fine.

Q. And just to be clear that there are no billing records on Exhibit No. 6?

MR. ANDERSON: There's no billing records because I haven't gotten a bill from him.

Q. Do you have any time records to show the amount of time that you've spent preparing your report in this case and the work that you've done in this case?

A. Not in a written form.

Q. Do you have them on a computer?

A. No.

Q. How do you maintain your time?

A. I'm sure I'm -- some time I will find the time to think about it and to estimate the time I spent for this and trial.

Q. Do you have any estimate at all of the time that you've spent preparing your report?

A. It's maybe around 30, 30 hours.

Q. All right.

MR. ANDERSON: He said preparing your report.

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You mean for all the work that he's done on Mullins or just working on the report?

MR. THOMAS: Specifically on the report.

MR. ANDERSON: Oh, just the report. He's asking just on the report.

A. Fifteen hours.

Q. Fifty?

A. Fifteen.

Q. Fifteen.

And a minute ago you said you spent 30 hours working on this matter. What did you do with the other 15 hours?

A. The preparation of -- of this deposition.

Q. So is it fair to understand that your best estimate of the amount of time that you've spent on the Mullins' case, recognizing that you spent a lot of time on prior cases, the total amount until we sat down here today is 30 hours?

MR. ANDERSON: Objection to the form of that question. Answer how much time you've spent on this case.

A. This is the time I would say I spent specifically for this specific case.

Q. Okay.

MR. ANDERSON: Okay.

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A. It is not the time that I was --

MR. ANDERSON: You've answered the question.

Q. I understand.

And, Doctor, did you meet with Mr. Anderson in preparation for your deposition?

A. Pardon?

Q. Did you meet with Mr. Anderson in preparation for your deposition?

A. Yes.

Q. And how many days?

A. Two-and-a-half maybe.

Q. And how much time did you spend over the two-and-a-half days meeting with Mr. Anderson to prepare for your deposition?

MR. ANDERSON: That's what he gave you.

A. Over all, 15 hours, about.

Q. You have other papers in front of you other than your written report we've marked as Exhibit 3. What else do you have with you?

A. That is my CV.

Q. Okay. May I see the CV that you brought, please? Do you mind if I look over your shoulder?

A. I didn't --

Q. Do you mind if I come over here and look over your shoulder?

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A. I can come to your side as well.
Q. That's fine.
(Klinge Exhibit No. 7 was marked for identification.)
Q. Doctor, we've marked as Deposition Exhibit No. 7 your copy of your CV, and I noticed you have some writing on it. Down at the bottom of the first page it says, about 20 with PROLENE as control. What does that mean?
A. In the list of publications that we made in all these years, several of these publications are dealing with the animal experiments where we tested different materials, and about 20 of these published articles use PROLENE as a control.
Q. And what does it mean to use PROLENE as a control?
A. When in 1994 we started our work with Ethicon to make a safer mesh, a lighter weight mesh, a better mesh, then we planned a series of experiments. And we need a control group which reflects the tissue response to -- to meshes as Marlex. And Marlex was the most common heavyweight mesh at that time, and a similar mesh was provided by Ethicon, and this was the PROLENE.
So in all -- in a lot of these experiments we agreed, together with the people from Ethicon where we

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made the plan for these analysis, that PROLENE served as a control group as the mesh with the highest risk for inflammation and scarring, and we received this PROLENE mesh from the people of Ethicon. The results of these animal experiments have widely been published, and over all we -- and this is the figure.
Q. Okay.
A. Twenty articles with PROLENE as a control group.
Q. And in different places you've made circles on different studies. Is that your effort to identify those studies where you used PROLENE as a control?
A. It should be these articles, yes.
Q. Okay.
A. I'm not sure in detail, but...
(Klinge Exhibit No. 8 was marked for identification.)
Q. Dr. Klinge, I'm going to hand you what's been marked as Deposition Exhibit No. 8, and represent to you that that's the expert report of Dr. Muehl. And, Ben, I apologize. I thought I had an extra copy for you.
MR. ANDERSON: That's all right.
Q. You've seen Deposition Exhibit No. 8 before?
A. Yes.
Q. Is it fair to understand that you're relying on

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the findings by Dr. Muehl in Exhibit No. 8 for your opinions in this case?
MR. ANDERSON: Objection to the form. Go ahead.
A. Some of the opinions are related to -- to these findings.
Q. Okay. Is there anything about the opinions expressed by Dr. Muehl in his report in Exhibit 8 that you believe to be inaccurate?
A. No.
(Klinge Exhibit No. 9 was marked for identification.)
Q. Okay. Let me show you now what I've marked as Deposition Exhibit No. 9. It's a 2014 research article titled, High Structural Stability of Textile Implants Prevents Pore Collapse and Preserves Effective Porosity at Strain. Again, Ben, I'm sorry. I for some reason don't have an extra copy of that.
MR. ANDERSON: That's all right.
Q. Do you recognize Exhibit No. 9?
A. Yes, I do.
Q. Is Exhibit No. 9 intended to represent the methodology for measurement of pore size that Dr. Muehl followed in preparing his report, Exhibit No. 8?
A. That's true.

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Q. Okay. Do you know of any differences in the methodology expressed in Exhibit No. 9, the article, and the report of Dr. Muehl, Exhibit No. 8?
A. I'm not aware of any.
Q. If you go down to the lower left hand of the first page of Exhibit No. 9, it states, "It is this excessive scar with consecutive contraction and thereby shrinkage of the mesh area that is related to the most -- related with the most serious complications, such as severe vaginal pain, dyspareunia, vaginal shortening, urethral obstruction, and SUI recurrence."
Since your last deposition have you undertaken to understand the rate of complications -- the rate at which these complications occur that you've identified in Exhibit 9?
MR. ANDERSON: Objection to form. Go ahead.
A. We didn't do any -- any -- we didn't do any study to identify the absolute rate of it.
Q. Okay. Other than your work in this report, which is Exhibit 9, since your last deposition, have you undertaken to determine the rate at which complications such as severe vaginal pain, dyspareunia, vaginal shortening, urethral obstruction and SUI recurrence happen?
MR. ANDERSON: Objection. Asked and answered.

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Didn't you just ask him that question?
Q. He answered it with respect to the study. I'm trying to find out generally whether he's made any investigation into the rates of complications that he's identified in Exhibit 9.
MR. ANDERSON: Okay. That's still asked and answered. Go ahead.
A. Only in the -- in the -- not specifically we made a study to identify the rate of these complications in clinical settings.
Q. Okay. So is it fair to understand that you can't give me any rates of complications that occur for stress urinary incontinence involving severe vaginal pain, dyspareunia, vaginal shortening, urethral obstruction and SUI recurrence?
A. To make this clear it has to be state or -- it has to be stated very clearly that the absolute number of complications after use of a textile implant in surgery, that it is not known and it is not possible to know this. Because it depends on the follow-up time, it depends on the cohort size that you are investigating. So there is no way in general to give you this number you are asking for.
Q. Okay. Then you say that surgical intervention is often required to alleviate the symptoms. What does

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"often" mean? How often?
A. For me the meaning is more than rare.
Q. And what does "rare" mean to you?
A. Less than often.
Q. Do you have any better description than that?
A. Rare is whether you believe that it is a real exception. If it's rare then you have the feeling that you have to tell someone because you have a special case.
Q. Is rare less than five percent?
A. Five percent of what? So it is not necessary to --
Q. Five percent --
MR. ANDERSON: Let him finish.
A. It is not possible to stick this to a certain figure without putting it into the context.
Q. Five percent of total implants.
MR. ANDERSON: Objection to form.
A. Five percent of total implants. If you -- if you apply a million implants, five percent means 50,000. 50,000. 50,000 is not rare.
Q. Is 10,000 -- I'm sorry.
A. It is a population of chance and the entire population of chance in 50,000.
Q. You have a good memory.

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A. You wouldn't agree to say that this is rare.
Q. Is 20,000 out of a million rare?
A. If it's my wife, no. It doesn't make any sense to struggle for one percent or two percent.
Q. Okay. Do you have --
A. It is too much.
Q. Okay. Is one in a million too much?
A. If it's unnecessary we should agree that it's too much.
Q. Okay. What is your definition of "unnecessary"?
A. Unnecessary is that you have no alternative, no better alternative. And if you have -- if you know that there are risks and you have alternatives there, then it is an unnecessary risk, yeah.
Q. Okay. In Exhibit No. 9, you and your coauthors measure the effective porosity and the textile porosity of the DynaMesh product at 600 microns, correct?
A. Yes.
Q. Did you attempt to measure the DynaMesh product at a thousand microns?
MR. ANDERSON: Objection. Don't answer the question. You had an opportunity to ask him about all these questions. I don't care. You just established on the record, and I'm glad you did,

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that this exact data was exactly what came out of the expert report of Muehl, which is exactly what came out of the expert report of Muehl back in 2013, and you had the ability, and your partner, Phil Combs, sat right in this chair where Raquel is and asked seven hours of questions of him, and then you asked seven hours of questions to him about this exact data.
MR. THOMAS: I'm not going to argue with you.
MR. ANDERSON: So he will not answer the question.
MR. THOMAS: Okay.
BY MR. THOMAS:
Q. Is the work that's done in Exhibit 9 exactly the same work that's contained in Exhibit 8?
A. So far I can see is the exhibit is more extense than the publication.
Q. Okay. Is it the same work though that makes up both exhibits?
A. Yes.
(Klinge Exhibit No. 10 was marked for identification.)
Q. Okay. Dr. Klinge, I'm going to hand you now what's been marked as Deposition Exhibit No. 10.
A. Thank you.

Q. Deposition Exhibit No. 10 is a document that counsel provided to me last week. Do you recognize this as a PowerPoint presentation you prepared?
A. Yes, I will.
Q. Can you tell when you gave this presentation?
A. I have to look in my documents where which of these presentations it was. It was a presentation I gave in Berlin on invitation of -- from Dr. Ismael, who is a gynecologist from the Charite in Berlin, and he made a conference at his department, and I was invited to give a lecture with this topic, how to define an optimum mesh.
Q. Which entry did you refer to?
A. This is 173.
MR. ANDERSON: Ismael is I-s-m-a-e-l, and Charite is C-h-a-r-i-t-e.
Q. And, for the record, your CV shows that you made this presentation on May the 8th; is that correct?
A. May 8th, yeah.
Q. Of 2015?
A. No, 2014. Sorry. It's a mistake. 2014.
Q. And, I'm sorry. I was looking when you answered. Who asked you to make this presentation?
A. Dr. Ismael. He was a gynecologist at the Virchow Hospital. It's one part of the Charite of the

University in Berlin.
Q. And who sponsored the conference?
A. It was sponsored by Dahlhausen.
Q. And what is Dahlhausen?
A. Dahlhausen is a distributor of DynaMesh product in Germany.
Q. And were you paid to make this presentation?
A. Yes.
Q. And how much were you paid to make this presentation?
A. Seven hundred euros.
Q. And who was your audience?
A. The audience would have been about 40 to 50 gynecologists.
Q. Okay. And those gynecologists practice in Berlin?
A. I don't know.
Q. Were there other speakers?
A. There has been other speakers, yes.
Q. At the time that you made your presentation on May the 8th, 2014, were other speakers also present?
A. There has been other speakers during this evening conference, yeah.
MR. ANDERSON: Sometimes if he says has been it translates as "were" for him.

MR. THOMAS: I understand.
MR. ANDERSON: You asked the question twice.
THE WITNESS: They are not sitting there any longer. So, sorry, yeah.
MR. ANDERSON: There were is another way of saying it. There were instead of has been.
THE WITNESS: Has been they are sitting still. Were is correct there. Thank you.
Q. Who else presented at that evening meeting?
A. I really do not remember. It was -- I have been there only a small time between the flights, because I have to leave at the same time Berlin. So I rushed in and rushed out, gave my presentation, answered some questions, and the rest of the conference were done by themselves.
Q. Okay. The title that I read, it says material, then it's German. What does the German statement say?
A. How to define the best mesh for my purpose. That is the problem every surgeon has.
Q. And when you say every surgeon has that problem, what do you mean by that?
A. Every surgeon who uses implants have to be -- have to select very consciously to find the safest, the best material for his specific purpose, and therefore it is necessary to ask for -- to look for some -- to look

for important information to be able to define the best mesh.
Q. Under that there is the statement, possible conflict of interest: Development of meshes in collaboration with Ethicon, Hamburg and FEG --
A. Textilltechnik.
Q. -- Aachen expert testimony.
Is that the disclosure of people you've worked for in the past?
A. Yes.
(Klinge Exhibit No. 10 was marked for identification.)
Q. Okay. And what was the goal of your presentation that you -- that's Exhibit 10?
MR. ANDERSON: Objection to form. Asked and answered. Go ahead.
A. The goal, you ask me -- please, can you repeat the question?
Q. What message were you trying to convey to your audience?
A. Sir, we can go throughout the first -- throughout the slides, the images. There are alternatives. Basic message is there are alternatives and the material has an impact on the outcome, and there are several issues that have to be addressed when

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discussing about the material, that is the polymer, that is the structure, that is the tissue response to the biomaterial, that is the function that is intended to be compensated by the implant, and therefore that is the effective porosity, and therefore a medical device, a textile medical device is a high-tech device which bears a lot of risks, and therefore these are the tools to define the -- the safest product. And, finally, it has to be related to the quality of surgery, of course, and to the quality of the patient.

Q. Why did you choose the Ethicon Prolift device to compare to the DynaMesh device?

A. Just because I had the images of these two alternatives.

Q. Okay. Did you believe that the Gynecare Prolift device was an alternative for the treatment of pelvic organ prolapse in May, 2014?

MR. ANDERSON: Objection to form. Go ahead.

A. I remember that we made a lot of -- that we -- there are a lot of differences between these products, between these textile structures.

Q. Do you know whether the Ethicon Prolift device was available for sale in May, 2014?

A. No.

Q. No, it wasn't or, no, you don't know?

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A. I don't know.

Q. Okay. Let's go to the next page. There are two slides here referring to inflammation correlates with fibrosis. Tell me what you're trying to describe to your audience here, please.

A. The upper right image, inflammation correlates with fibrosis. It was the analysis of a thousand explanted hernia devices and showed that you have a close correlation between inflammation and connective tissue, inflammation of the YX and connective tissue scarring on the XX, and you see the more inflammation, the more connective tissue.

The -- we have three different markings for the -- for different devices. The red ones are many plaque three-dimensional structures where we know that we have almost no big distance between the fibers, and they all -- the histological reaction for all of these plaques, almost all of these plaques, showed that you have a high risk for inflammation and a high risk for scarring.

You have the blue markings. These are what we would call lightweight large pore meshes, and significantly less inflammation, significantly less connective tissue. And in the middle of the greens are the small pore -- small pore heavyweight meshes, so the

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class two meshes.

You see there are some which performs quite good in some patients, but the risk is significantly higher in comparison to the blue. It's better than the red. You over all see that there is some variation, it's not a strict line, but you have an individual response of various patients to the materials. It can be influenced by infection, for example.

So even if you have a very, very good material, in case of infections you will see a lot of inflammation and maybe more scarring. So you see that the risk for large-pore constructions is the lowest, for the plaques it's the highest, and in between you have a higher risk than compared to the blue.

This is -- in this image you just see the correlation between inflammation and connective tissue, and in the next one I added the next information whether there is bridging fibrosis, whether the pores are completely filled by scar tissue.

And there you can see on the third X that the blues, or that the reds, the plaques they are completely bridged. There is no pore without any scarring in filling out the entire pore. The blues have the lowest risks, the greens in between.

Q. And, Doctor, have you ever made any attempt to

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determine the extent to which the increased inflammation that you show in these two slides equates with increased reports of pain in patients?

A. That was one of the starting points when we made our studies in the '90s that we -- that we observed that a lot of people have chronic pain, and then when we look to the explants 90 percent of these explants are heavyweight, small pores, so from the class PROLENE at Marlex.

And after the introduction of Vypro as a large-pore mesh, and Ultrapro, we rarely got explants because of pain after implantation of these materials.

So, yes, we know that the -- that 90 percent of patients with chronic pain could be related to the use of heavyweight small-pore meshes.

Q. Have you ever studied the extent to which there is increased inflammation and fibrosis associated with meshes that are not -- that are removed for reasons other than pain?

MR. ANDERSON: Objection to form.

A. Yes.

Q. And have you compared the two to determine the extent to which the increased inflammatory response and fibrosis correlates with pain.

A. The pain issue was mainly limited or related to

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the use of small-pore meshes. So you have an increased risk for pain and you have an increased inflammation and connective tissue in this group of -- of explants.
Q. I understand that's your opinion. Have you published a study on that? That's what I want to know.
A. Yes, we did.
Q. And that's the 2002 study, did I get that right?
A. The last time it was the publication 623 explants for Klosterhalfen and me.
Q. Let's go to the slide that says textile characteristics, please. You list six different characteristics for the textiles. That's the type of material that's used in mesh. Is that correct?
A. At least six. There is the last indicating that there are some more or are you on the left or --
Q. I'm on the left, exactly where you are.
A. On the left, yeah. So I started to make a list of textile properties, but then indicating that there are lots of more.
Q. And when you say pore size has to be considered as most relevant for biocompatibility, what do you mean by that?
A. The distance between the filaments or the pore size of one millimeter in all direction has a high power

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to predict the tissue response in relation to inflammation and fibrosis.
Q. Okay. If you'd go to the next page, please. Under outcome, what are you trying to show in these last series of slides, beginning with outcome?
A. The point to be discussed here is what is the impact of the material on the outcome. And this depends on the conditions. You're able with an awful surgery to create all complications without the need of an implant, and even with the best implant you can create a lot of complications.
This makes it so difficult to identify in clinical studies the impact of the material on the outcome. So you have this mix-up of surgery and there are of course patients where the indications may be not the best and the good material.
But in the conferences there are a lot of experts, and to all my colleagues doing an excellent surgery, treating excellent patients, they experience sometimes some complications. And looking for the reasons for these complications, in these patients with excellent surgery, excellent biology of the patient, the impact of the material for the outcome can be considerably high. It can go up to 70 percent, 80 percent.

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So the impact of the material on the outcome, particularly in patients who know how to treat and in good patients is very, very high, and in these patients it is even more important to think about the material. That is the point here.
Q. Doctor, when you made this presentation to these doctors in 2014, did you discuss with them the risk of mesh implantation on the nerves in the pelvic floor? I don't see any slides on that.
A. No. It is a limited time and usually you'll see it was for 20 minutes. And if you are counting the imagines I usually have to talk as in the film, 21 images per second or per minute, and I've been off, I suppose.
(Klinge Exhibit No. 11 was marked for identification.)
Q. Let me show you what has been marked as Exhibit 11, and it's another PowerPoint presentation that was provided to me by counsel. It's very similar to the one that you just provided me. Can you tell me where you gave that presentation?
A. If I'm correct, this is a presentation a week before I was invited by the Endoscopic Urogynecologist Society that met at Norwich in U.K.
Q. Okay.

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A. And I was asked to, during the conference, to give a presentation by the head of the conference.
Q. And did you go there at the request of Dahlhausen?
A. I went there on request of this, of this head of the conference, but Dahlhausen or the FEG supported this travel.
Q. Did they pay you to attend 700 euros?
A. No.
Q. Did they pay your expenses to attend?
A. Expenses, yeah.
Q. Did you receive any other compensation for the presentation of the -- the presentation that's Exhibit No. 11?
A. No.
Q. While the slides are a little different the message appears to me to be the same. Is it a similar message for Exhibit No. 11 as it was for Exhibit 10?
A. You will always find that the facts are quite similar in all these presentations during all the past 20 years. However, it's an evolving of ideas and the meshes -- the speaking words, the words for the conferences, they changed.
Q. Okay.
MR. THOMAS: Let's go off the record, please.

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I need to take a break.
MR. ANDERSON: Okay. We shall take a break.
(Recess from 11:33 until 11:41 a.m.)
BY MR. THOMAS:
Q. Doctor, what does it mean to be an academic editor?
A. Pardon?
Q. What does it mean to be an academic editor of a paper?
A. Elder?
Q. Academic editor.
MR. ANDERSON: Editor.
A. Editor. I don't know the official definition of this.
(Klinge Exhibit No. 12 was marked for identification.)
Q. Okay. Let me hand you what's been marked as Deposition Exhibit No. 12. Deposition Exhibit No. 12 is a review article June 27th, 2014, accepted October 3l, 2014, by Barski and Deng, where you're shown as the academic editor.
A. Yes. So my task is I was asked to take care of this article, and the first is you have to decide whether it fits in the scope of the journal, or the specific issue, or to just reject it as out of the

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scope.
If it is within the scope of this issue, then you have to send it to some reviewers, and then you have to wait until the reviewers ask or send back their statements. Then you pass over these statements to the authors and you are waiting until they send a revised manuscript. Then you send this revised manuscript to the reviewers, whether they accepted it or not. And then you are finished.
Q. Okay.
A. Then you have to say the reviewers agree, then you send it as last message to the authors. It is accepted.
Q. Did you review Exhibit No. 12 before it was published?
A. Yeah. Surely I read it, yeah.
Q. Did you comment on Exhibit No. 12 before it was published?
A. I didn't -- I didn't was a reviewer for this manuscript, I just organized the review process for this.
Q. Okay. But did you offer any comments at all to the authors about this Exhibit 12?
A. For this, no.
Q. Okay. In your practice when you review papers

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as an academic editor, if you find things in there with which you disagree, do you advise the authors of your disagreements?
MR. ANDERSON: Objection to form. Go ahead.
A. I rarely act as an academic editor. This was an exception to do so. Usually I'm busy just as a reviewer and I give my comments and statements and recommendations to an editor.
Q. Why did you act as academic editor for Exhibit No. 12?
A. I was asked and invited by Dr. Otto. He was the invited editor of this issue of this journal, and he asked several colleagues to help him in this editing process for this issue.
Q. And Dr. Otto is the colleague that you published with that we've talked about before?
A. No.
Q. Different Dr. Otto.
A. Yes.
Q. Okay. Who was the Dr. Otto that asked you to participate in Exhibit No. 12?
MR. ANDERSON: What was his name? Which Otto was this?
THE WITNESS: The last one.
MR. ANDERSON: Yes.

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A. This one is a urologist, I think Thomas, Thomas Otto from Neuss, close to Dusseldorf. He's their head of the department for urology.
Q. Okay. And do you know Dr. Barski, the first named author?
A. I know that it is a resident at this department --
Q. Okay.
A. -- there.
Q. Have you discussed with either Dr. Barski or Dr. Deng the contents of Exhibit 12?
A. No.
Q. Do you have any reason to believe that this review article, Exhibit 12, is not a good statement of the medicine of the management of mesh complications after SUI and POP repair, review and analysis of the current literature?
MR. ANDERSON: Object to the form of the question.
A. I don't have an opinion to this, except we read it together.
(Klinge Exhibit No. 13 was marked for identification.)
Q. Doctor, I've handed you maybe two copies, what I've marked as Deposition Exhibit No. 13. Deposition

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Exhibit No. 13 is a study published by William S. Cobb, and others, in the Journal of American College of Surgery in 2015. Are you familiar with this study?
A. I'm not sure.
Q. Do you know Dr. Cobb?
A. I know his name.
Q. Okay. Have you ever collaborated with Dr. Cobb on any projects?
A. No.
Q. Are you aware that Dr. Cobb, at about the same time that you and Dr. Klosterhalfen wrote your article in 2005, that Dr. Cobb and Dr. Heniford wrote a similar paper, The Argument For Lightweight Polypropylene Mesh in Hernia Repair. Do you remember that?
A. We have been surprised about this, yeah.
Q. Okay. You said you don't know if you've seen Exhibit No. 13. Can you take a minute and look through it and see if that refreshes your recollection about whether you've seen it before? I want to give you enough time before I ask you questions about it. If you've seen it before, it's fine. If you haven't -- as you're looking through it, does it ring a bell?
A. Maybe I've reviewed or I read just the abstract. But I didn't -- didn't have a look in detail to all the points here.

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Q. Okay. If you look at the study design it's a retrospective review performed to include elective retromuscular mesh repairs of complex incisional hernias from August 2006 to 2013. Demographics, operative details and post-operative events, including wound events, surgical site infections and recurrences were reported. And over a seven-year period they looked at 255 retromuscular mesh repairs of midline incisional defects, and they analyzed various results, recurrences and surgical site infections from that group; is that correct?
A. As you read, as it's written in the abstract.
Q. This study finds that when evaluating polypropylene meshes recurrence was more likely with lightweight mesh, 22.9 percent, versus midweight mesh, 10.6 percent. Do you see that?
A. I see this.
Q. Are you aware of other studies finding an increased rate of recurrence with lightweight mesh compared to midweight mesh in hernia repair?
MR. ANDERSON: Objection to form. Go ahead.
A. Regardless that there is no clear definition what is lightweight and midweight and heavyweight, I am aware of studies showing differences in the outcome in regard to recurrences between meshes.

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The summarized conclusion is difficult, and the main concern when taking these studies is that it is a complete mix-up of sources for recurrences. They are underpowered usually. It is very, very difficult to relate this outcome to the material, very, very difficult.
Q. Do you agree with the statement generally that when you evaluate polypropylene meshes that hernia recurrence is more likely with lightweight mesh than midweight mesh? Do you agree with that statement?
MR. ANDERSON: Again, objection.
A. As a general statement that all polypropylene lightweight meshes have a higher risk for recurrences than midweight, I cannot agree to this.
Q. Why not?
A. As I told you, there is no clear definition which mesh is used, which technique is used. It is a mix-up of various confounders that interact with a -- with the development of a recurrence. The outcome has to be followed for a long period, probably longer than seven years.
So all of these limitations of a clinical study, 255 patients, the statistical power is too low to -- to give any certain -- to allow any certain statement on the outcome there. So you can describe the result as

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it is, but any linkage between two things, it is -- I wouldn't agree to this.
Q. Okay. Turn to Page 610, please, of Exhibit 13. And on the left side, right in the middle, it says, "With respect to mesh type recurrence rates were 16.2 percent with synthetic mesh, 17.1 percent for bioabsorbable mesh, and 25 percent for biologic mesh. Of the recurrences seen in the permanent mesh group, two-thirds occurred in the lightweight mesh patients. When evaluating polypropylene meshes alone, a significant difference in incidence of recurrence was seen when comparing lightweight mesh, (22.9 percent) and mid-weight mesh (6.10 percent) (p equals 0.045). The mechanism of recurrence was central mesh fracture or failure in nearly half of the recurrences."
As you read that, have you found or seen any other studies making similar findings about central mesh fracture or failure in lightweight meshes used to treat hernia patients?
A. The central mesh rupture firstly has been mentioned at one of the Suvretta conferences that has been sponsored by Ethicon in about 2000, in around 2000, by Chiapas. He was the first mentioning central mesh rupture. These has been Aachen results because we realized that if you have a -- if you use Vypro as a

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prototype of a material reduced mesh, in the condition that you cannot close the fascia on top of it, that we realize that in some patients you have a central mesh rupture, and this was presented at this conference there.

Meanwhile, there has been publications about Ultrapro and there has been publications of central mesh rupture in heavyweight meshes as well. So there are several studies already discussing mentioning the problem of central mesh rupture.

Q. Okay. Have you been involved in any studies discussing central mesh failure or rupture?

A. I was approached by a Belgian surgeon and by Chiapas to collect data about central mesh rupture, but it was not -- there is no protocol of a study, and it was not finished yet.

Q. Is it still in process?

A. We are still thinking about it.

Q. And what did you do to gather data about central mesh failures or ruptures?

A. First of all, we presented the problem to the audience and we presented the problem to the people from Ethicon, and I know that the Belgium surgeons presented the problem to Ethicon as well, in particularly as the Ultrapro mesh of Ethicon has a specific problem to allow

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a central mesh rupture.

This was -- has been discussed by me and by others with the -- with people from Ethicon, and at one of the last conferences I was told by someone from Ethicon that at the end of this year they will release a modification of the current Ultrapro textile structure. I was asked to keep this information confident, but I hope in your hands it is still confident.

Q. When you say you presented this information to the audience, what audience did you speak to?

A. In particularly I remember a meeting of the German Hernia Society in Baden-Baden where this was a hot topic in the presentations and discussions there raised by various people there.

Q. And when you say it was a "hot issue," what is the hot issue? Is it central mesh failure in lightweight meshes?

A. In the specific lightweight mesh of Ultrapro, because the textile bending allows very easily a splitting when you are putting load to it in between the fibers.

In 90, perpendicular to this direction, it is very difficult to make a rupture of the mesh, but to open the textile bindings of this structure it's very easy. And you have similar differences for PROLENE and

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even more for Marlex. In one direction it is very, very strong, and in the other it has a very low resistance for subsequent tearing force.

Q. Have you analyzed other manufacturers' lightweight meshes to see the extent to which those lightweight meshes are involved in central mesh failures?

MR. ANDERSON: Objection. Go ahead.

A. We didn't make a systematic analysis of other meshes.

Q. Is that because the surgeons to whom you spoke used Ultrapro -- or strike that.

Why didn't you look at other meshes to -- well, strike that again.

Why did you not look at other lightweight meshes used in hernia repair to determine the extent to which they were involved in central mesh failures?

MR. ANDERSON: Objection to form. Go ahead.

A. We have clearly showed that you have to look to central mesh rupture, you have clearly showed that you have to create a textile analysis in two directions to identify the weakness of a textile construction. We have presented this to the public, how to analyze the problem, how to analyze and how to solve it, and we didn't -- I didn't focus my work on this topic, just

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because of time.

Q. Okay. Have others written on the issue of central mesh failure involving lightweight mesh for hernia repair for products other than Ethicon products?

A. Sometimes it is not clear which products are used. Usually it is a -- these are retrospective analysis of central mesh ruptures. It's only a handful of these studies. Sometimes it is said that it is Ultrapro and -- but sometimes it is not known which material.

Q. Do you know the extent to which lightweight large-pore meshes from other manufacturers are involved in central mesh failure in hernia repair?

MR. ANDERSON: Objection to form.

A. I have no data about it.

Q. If you go to the last page, Page 612 of the study, it states that, at the top of the page, "The failure of these meshes is aggravated by bridged repairs and in morbidly obese patients. In our experience, 20 of the 43 recurrences were due to central failures of lightweight mesh. Our current practice has changed and now we use a macroporous, midweight mesh construct with a density of polypropylene of 45 grams per meter squared."

Do you know of other physician groups who have

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stopped using lightweight mesh because of the risk of central mesh failure?
MR. ANDERSON: Objection to form. Go ahead.
A. I remember that there are surgeons stopping to use in Germany Ultrapro for the use of incisional hernias where you cannot close the fascia because of these reports of this problem, and they went over or they preferred to use other materials.
Q. Okay. And what other materials do you understand they prefer to use?
A. There are -- I don't know exactly specifically for the specific surgeons, but there are several other alternatives on the market that doesn't have this problem, specific problem, of the Ultrapro.
Q. In 2013, do you have any idea of the market share that Ultrapro had for hernia repair in Germany?
A. I estimate that it is, depending on the type of hernia, for the groin it is maybe different to incisional hernia. But it is said to have around 70 percent.
Q. And what other types of meshes make up the 30 percent in 2013?
A. In Germany there is a -- a big competitor is Covidien.
Q. Does Covidien make a lightweight, large-pore

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mesh that is a competitor to Ultrapro?
A. All the manufacturers are coming up with lightweight meshes, some sort of lightweight meshes they offer. But Covidien is one of the biggest, made by Medtronic, bought by Medtronic, and another major manufacturer is Braun.
Q. Brown?
MR. ANDERSON: Braun.
Q. B-r-a-u-n?
A. Yeah, Braun.
Q. Are you aware of reports of central mesh failure with the Covidien lightweight large-pore mesh in hernia repair?
A. No.
Q. Are you aware of central mesh failure for lightweight mesh manufactured by Braun?
A. No.
Q. For hernia repair?
A. No.
Q. Dr. Cobb states in that last paragraph that our current practice has changed and we now use a macroporous midweight mesh construct with a density of polypropylene of 45 grams per meter squared.
Do you find any flaw in the medical judgment of Dr. Cobb and his group to use a macroporous midweight

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mesh construct with a density of polypropylene of 45 grams per meter squared?
A. The major or the critical point is not the weight. The critical point is the textile construction, whether you managed to make the linkage between the filament strong enough to withstand a subsequent tearing force. And this can be realized with more weight, but it can be realized with less weight. So to -- for the prevention of a central mesh rupture, the quality of the textile construction is decisive.
Q. Do you have any criticism of Dr. Cobb's group using a polypropylene mesh for the repair of hernias?
A. I have no opinion to this.
Q. No opinion at all?
A. No, it is too complex. So for what hernia, in which construction, which polymer, which polypropylene. So you have to discuss it, what are the alternatives for them of what to do. So it's -- I'm not able to give a short answer to this.
Q. Okay. You've not performed surgery yourself since 2006, correct?
A. That is correct.
Q. Do you give advice to surgeons today about the proper mesh used to treat incisional hernias?
A. I don't think that I ever advised a colleague

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to use a specific product or a specific textile. I usually present our research data of the past 20 years. I present our experiences which we made for these meshes, and then I presented the facts, and I usually left it up to the surgeon to draw his conclusions of it.
Q. Did you ever tell any of your surgical colleagues not to use a specific kind of mesh for hernia repair?
A. Surely I -- I indicated a higher risk for a mesh.
Q. And the higher risk you're talking about is what you've talked about in your presentations?
MR. ANDERSON: Objection. As to which presentation?
Q. The presentations over the last 20 years to which you've just referred.
A. Of course you will find, you have a lot of my presentations already in your documents, you will find there some slides showing the problem of central mesh rupture, of, yeah. You will find it and I presented it to the audience.
Q. Okay. And you agree that hernia repairs for a hernia recurrence increase the likelihood of a surgical site infection?
A. The redo generally is considered as risk factor

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for SSE, SSI.
(Klinge Exhibit No. 14 was marked for identification.)
Q. Let me show you now what I've marked as deposition Exhibit No. 14.
A. Yes.
Q. Exhibit No. 14 is a study published in the International Journal of Surgery, first author, Weyhe, W-e-y-h-e, second author the same William Cobb we've talked about before. Are you familiar with this study?
A. Yes.
Q. And, for the record, this study is published in July of 2015. Did you find this study on your own or was it provided to you?
A. I'm sorry?
Q. Did you find this study on your own or was it provided to you?
A. No, I received it by -- from Dirk Weyhe. He discussed this issue with me during the last year several times.
Q. Were you aware that the authors were doing this study prior to the publication?
A. Pardon?
Q. Were you aware that the authors were doing this study prior to the time it was published?

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A. Usually they do the experiments before publishing.
Q. But did they talk to you about it?
A. They presented it in some of the conferences already and they tried very hard to find a journal that accepted this study there, and finally they have been happy there because maybe it is so sophisticated in the experimental setting that they have some difficulties to pass reviewers.
Q. Tell me what you know about the difficulties they had in getting this study published.
A. I don't know any details.
Q. Okay. And why do you suggest they had difficulties in getting the study published?
A. I don't have any opinion to this.
Q. Okay. If you go to Page 47, which is the second page of Exhibit No. 14, down towards the bottom of the introduction, it says, "The pore size of commercially available meshes in hernia surgery ranges from 0.4 millimeters to greater than 3.6 millimeters, while the majority of the first mesh generation reach a pore size of about .8 millimeters. According to the International EndoHernia Society, IEHS, pore sizes of 1.0 to 1.5 millimeters are recommended."
Do you agree with that statement, that's what

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the International EndoHernia Society recommends?
A. The International EndoHernia Society made a statement about the material and the meshes, and they indeed recommend large pore meshes, but with a lot of comments on the limitations to define or to make these statements.
Q. But is it true that the International EndoHernia Society recommends pore sizes of 1.0 to 1.5 millimeters?
A. As I told you, if you're going to this text where they publish it, I think in the surgical -- in Surgical Endoscopy, you have the entire text, several pages there, and somewhere there is a recommendation for this use of these large-pore meshes, yes.
Q. In the range of 1.0 to 1.5 millimeters, true?
A. Yeah; but with a lot of further comments to this.
Q. Okay. "To our knowledge the correlation between elasticity, stability porosity of mesh constructions and shrinkage is not proven systematically up to now."
Do you agree with that statement?
A. At this time point, no.
Q. And tell me why you don't agree with that.
A. Because we presented already or we published

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already the consequence of mechanical loads to the structure of the pores.
Q. And that's the Muehl testing that we've talked about so much in the past?
A. Muehl testing and the -- the publication from last year, I think.
Q. Okay. Any other publications about which you're aware that cause you to disagree with that statement?
A. Muwalli (phonetic).
Q. And is that the Muwalli (phonetic) paper that uses uniaxial testing?
A. I have to -- I have to see the paper. The group published so many things, but I remember that they -- the investigated mechanical loads too as well. There are some from Vinadian (phonetic), from an Australian group, that looked to the changes in meshes after applying loads to it.
Q. What about the issue of stability porosity of mesh constructions and shrinkage is not proven systematically up to now?
A. I would agree to this.
Q. Okay.
A. Sufficiently.
Q. So what they set out to do in this study was to

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define the optimal range of pore size, based on the post-operative assessment of tissue integration and shrinkage behavior in a hernia minipigs model. Do you have any quarrel with the choice of the minipig as a model?

MR. ANDERSON: Objection. Go ahead.

A. The minipig offers some -- some good options. The placement of the mesh in the abdominal wall offers some -- some options. Everything has a lot of limitations as well, so therefore you have to -- to see it in which context. What do you want to see, what do you want to measure?

Q. Since you reviewed this study before, you're aware that the meshes that are analyzed here are specifically provided by Covidien and they were devised for this study. Did you know that?

A. No.

Q. Let me direct your attention to the --

A. I know some of the authors are working for Covidien, so therefore it is linked to Covidien. So, yeah, I know.

Q. If you go back to Page 52, under the conflict of interest. It's the last page of the study.

A. Last?

Q. Excuse me. The next to the last page. Next to

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the last page, I'm sorry, under conflict of interest. It says Covidien produced the customized meshes used in this study.

A. I think so, yeah.

Q. Okay. And if you go back to Page 48, it shows the measurements of the pores for each of the meshes that were studied there. Do you see that?

A. No, not yet.

Q. Page 48?

MR. ANDERSON: This one with the green on it.

A. Yeah.

MR. ANDERSON: What section, Dave?

MR. THOMAS: I'm on Table 1.

MR. ANDERSON: Okay, thanks.

Q. Do you see how the authors in Exhibit No. 14 measured pore size?

A. Yes.

Q. What is warp and weft?

A. So far I remember is the warp fibers are those coming from the machine. So in a textile hosiery and every -- most of the mesh construction of textile hosiery, the fibers are coming from the ground, from the machine, and these are the warp fibers, and there are no weft fibers, different to the clothing. There you have some weft fibers crossing all the other lines and

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combining these filaments.

In this -- in these textile constructions the linkage is done just by turning one filament around the other. So there that creates some sort of binding there, but you don't have this weft. But, to make it easier for a reader to understand it, it is helpful to discuss on the one hand this is the warp direction.

MR. ANDERSON: Going up and down.

A. Up and down. And perpendicular to this, this is the weft direction. The critical point is, if you are tearing a mesh perpendicular to the warp direction, you have to cut every filament. That is almost impossible to do it by hand. If you put a load to it in direction to the warp direction you can split it just by opening these bindings. There is no filament as a weft running across. And this opening of the bindings is in some textiles very easy to manage as in Ultrapro. You only need very small forces to split the mesh when putting a load in this direction, in line with the warp. If you make it -- if you place it perpendicular to this, it is very strong.

Q. Okay. Do you see here -- you're referring to the tensile strength of the Ultrapro when you're making that description; is that right?

MR. ANDERSON: Objection.

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A. I don't get --

Q. You were talking about how if the mesh fails then it's very easy for the mesh failure to expand. Was that the point of your testimony?

A. The splitting of some textile constructions can be done very easy, but only in one direction, to open these loops, to open these bindings.

Q. Okay. And --

A. And, therefore, it is important to know that there are two different directions, though it is not correct to talk from a weft.

Q. Did as a part of your work with Dr. Muehl you measure the strength of the meshes in two different directions for the TVT device?

A. For the TVT as a sling, this was measured so far I remember just as a sling.

Q. Okay.

A. But if you rely to the measurements of the Prolift, or Prolift M, where you have a flat-mesh area, there we did it in two directions.

Q. You see in Table 1 the authors in this study measure the tensile strength at breaking point for each of these customized meshes in the warp direction and the weft direction. Do you see that?

A. Yeah.

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Q. And they're different, aren't they?
A. They are different.
Q. And is this the same difference in breaking strength that you discussed a moment ago when we were talking about Ultrapro, the difference in breaking strength depending on which direction the load is applied?
A. It is this difference between warp and weft direction that the materials have different strength in regard. And you'll see here in this, the last part one, there you have tremendous differences. So the differences may vary in the middle.
Q. Do you know the extent to which the differences in Ultrapro -- strike that.
Do you know how the differences in Ultrapro's breaking strength compare to the five meshes that are contained in Table 1?
A. I know that we have published the data for Ultrapro, but I don't recall it in the moment.
Q. And the data that you have published on Ultrapro was what?
A. In many of our publications we started in the section material and methods with a table that gives the textile, the data of the textile analyzers there. And there, in many of the publications, there has been a

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separate description of the tensile strength in the two directions. We didn't talk of warp and weft direction, but horizontal and vertically direction.
Q. Do you recall, as you sit here today, any of those studies that I could go find that information?
MR. ANDERSON: Objection. Don't answer the question. You're only allowed to ask the doctor between 2013 to the present. You've had plenty of time to ask him about all the studies that are in his things over the last 30 hours plus of questioning him. He's not going to answer it.
MR. THOMAS: Okay. We'll see.
MR. ANDERSON: Okay.
BY MR. THOMAS:
Q. Since 2013, when your deposition was last taken, have you published any studies on Ultrapro where you identify the tensile strength of Ultrapro in the vertical and horizontal directions, or warp and weft?
A. No, except -- except the study from Muehl is Prolift M where Ultrapro was used. So in this article you will find some data related to this issue.
MR. ANDERSON: Thus my objection.
MR. THOMAS: I'm sorry. I have to stop again.
MR. ANDERSON: Okay.
(Recess from time 12:33 until 12:39 p.m.)

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BY MR. THOMAS:
Q. Page 51, under discussion. Authors state, "It is hypothesized that the use of light meshes may reduce undesirable clinical side effects. A series of meta-analysis gathered data from randomized controlled trials that compared lightweight and heavyweight meshes in inguinal and abdominal hernia repair. No significant differences" --
MR. ANDERSON: Where are you reading? I'm on the wrong page, I guess.
MR. THOMAS: Page 51.
MR. ANDERSON: 51, okay. Sorry. I thought you said 15. Go ahead.
Q. Let me start over again. Down under discussion. "It is hypothesized that the use of light meshes may reduce undesirable clinical side effects. A series of meta-analysis gathered data from randomized controlled trials that compared lightweight and heavyweight meshes in inguinal and abdominal hernia repair. No significant differences were found or only slight advantages were detected after using lightweight meshes and most advantages occurred only during the early post-operative period."
Do you agree with that statement?
MR. ANDERSON: Objection to form.

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A. In the -- in the meaning that you consider the limitations of these randomized control trials and meta-analyses to -- to describe these differences, to find these differences, to prove these differences in general, this is a description of what currently is found in some of these studies. However, you have to make very, very clear that comparison of materials with these clinical studies is hardly possible in general, and therefore the absence of a difference can never be taken as confirmation that there is no effect. That would be unscientifically.
Q. The next paragraph, top of the page, says, "While it is quite clear that a macroporous mesh improves biocompatibility in terms of mesh integration, the optimal pore size remains unknown."
Do you agree with that?
A. Optimum pore size, it is his opinion, but to make it -- give a comment on this it has to be clear what is meant by or what is the meaning of pore size, how is it measured, in which regard. And what is clear is the larger the pore, the safer, the less risk. This is quite clear. Optimum for what purpose? The search for an optimum for just one figure, it is -- it doesn't make sense.
Q. Do you agree that as the pore size gets larger

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that you increase the risk of higher rates of shrinkage?
A. No.
Q. So the results of his studies where they conclude that large pore size and lack of stability in lightweight meshes leads to shrinkage you disagree with?
MR. ANDERSON: Objection. Misstating. Go ahead. Objection.
A. He has certain findings and these are -- I have to accept as a fact. What is missing in this article, from my point of view, or what is not presented in this article, is if you are discussing shrinkage, this means that you have a deformation of the mesh. This can be done either by mechanical forces or it can be done by contraction of the scar. And the mechanical forces in indeed the large-pore meshes usually are more pliable, more flexible, and therefore they provide usually less resistance to mechanical deformation.
On the other hand, the large-pore meshes in use is significantly less scar and therefore you will have less scarry shrinkage in large-pore materials in comparison to others. There may be experimental settings where this is compensated or there may be experimental settings where one dominates over the other, but it has to be considered both.
Q. Are you aware of any studies using the

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methodology you just described to compare shrinkage in large-pore mesh and small-pore mesh?
A. Studies that -- that are looking for the stability of the textile structure with its consequences, I do not remember that there are -- that there are these studies. The reason, of course, is that in -- in hernia surgery we have tension-free conditions and therefore this issue is not so relevant.
Q. Is Exhibit No. 14 helpful to mesh designers in understanding the forces and issues associated with different types of mesh for hernia repair?
A. Of course.
Q. And in what regards is it helpful?
A. This study acknowledged that you need or that the importance of a structure or what I proposed to Dirk Weyhe to name to call it structural stability. But this is maybe not the best word for it.
But the resistance of a textile, or the influence of elongation, stretchability, pore collapse to the deformation of these meshes. This is a -- this is a study showing that this is important to consider this.
Q. Okay. So is it fair to understand that in addition to pore size that we've talked about a lot over the years, that the structural stability of the material

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used to construct the mesh is of importance to maintaining those pore sizes in vivo?
A. Again, please.
(The question was read by the Reporter.)
A. The structural stability, one aspect of a structural stable textile is that you have a higher resistance against pore collapse and a load. But structural stability may mean more. It has to be defined. It is just how the textile responds to a mechanical load. This is the -- the critical point. And this hasn't been a critical point for hernia meshes, but it is a critical point for pelvic floor meshes. And this is the basic concept that has to be evaluated when using hernia meshes in a condition where you have some -- some load to it.
Q. So are you saying the structural stability of the mesh is not a critical point for hernia meshes?
A. The structural -- it has not been in the studying in the -- in the scientific world over years. It was or it was regarded as tension free. So the -- the change of a textile, if you place it in a flat mesh area, the change of the textile in response to -- to some mechanical loads was not in the focus of the scientific world.
Q. Is it appropriate for it to be in the focus in

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the hernia area?
A. Is it appropriate?
Q. Yes.
MR. ANDERSON: Should have been.
A. It depends on the hernia, on the type of hernia, and the location. There are -- there are indications in the abdominal wall as well where you have to consider forces, and for these indications you have to consider this, yes.
Q. And why is the structural stability a critical point for pelvic floor meshes?
A. Because the implants so far I know that are used in the pelvic floor they replace -- they are thought to replace some ligaments. They are placed in an area where you have movement, you have changes in the position of the organs there. So you have more mobility, more mechanical forces to be considered in this, in the pelvic floor. It cannot be considered as tension free.
Q. Since your deposition in 2013, have you undertaken to understand the forces present in the pelvic floor?
A. We didn't make specific studies to define the forces in the pelvic floor.
Q. Does Exhibit No. 14 suggest to you the need for

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additional studies in this area?
A. Does it suggest that?
Q. Are there any questions that are raised by Exhibit No. 14 that you think can be answered by any new studies on the issue of shrinkage on the large pore lack of stability in lightweight meshes?
A. It is the experience of any researcher that when you finish the study you have a lot of more questions to be solved there.
Q. And exactly right. That's my question here. What questions are posed by Exhibit No. 14 that you think bear additional study?
MR. ANDERSON: Objection. Go ahead.
A. You have to look in -- maybe you have to look in other models. You have to characterize more better the pores or the distance between the fibers. You have to consider the anisotropy, what happens there. You have to consider the forces, you have to consider a lot of these things. So we can create several new studies for scientific purpose.
Q. Is this the first study about which you're aware, Exhibit No. 14, that makes the finding that large pore size and lack of stability in lightweight meshes leads to shrinkage?
MR. ANDERSON: Objection to the

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characterization of this and objection to anything prior to 2013. You can answer for anything that you're aware of since 2013. Do you understand my objection?
THE WITNESS: Yeah.
Q. Okay.
A. I don't recall any others.
Q. Okay. Since 2013, have you analyzed the extent to which mesh in either hernia repair or pelvic floor repair interact with nerves?
MR. ANDERSON: Objection to the form of the question.
A. Analyzed -- if you're thinking of a specific study looking to nerves, no.
Q. Okay. Have you spoken, since your deposition in 2013, on the risks to nerves presented by implantation of hernia mesh or pelvic floor mesh?
A. Have you spoken -- you mean on conferences?
Q. Conferences, presentations of any kind.
A. I don't recall that this was a specific topic.
Q. Okay. Do you recall any PowerPoint presentations, any slides since your last deposition, in 2013, where the issue of mesh and its impact on nerves is discussed?
MR. ANDERSON: Objection to form.

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A. The relevance of scar, of the scarring as a consequence of meshes and its consequences for chronic pain is a message of the past 20 years, but I do not recall that it is a specific issue that I had to cover in the past two years.
Q. Have you ever met Dr. Iakovlev?
A. I have seen him, but I -- that's not I think a meeting. I just saw him.
Q. Did you speak with him?
A. No.
Q. Have you spoken with Dr. Iakovlev about his report?
A. No.
Q. For what purpose did you review his report?
MR. ANDERSON: Objection to the form.
A. In fact, I was interested to see whether he could or whether he confirms all the things that we have seen or analyzed in the past 20 years or whether he found something different.
Q. And what did you decide upon your review of his report?
A. What did what?
Q. What did you decide upon your review of his report?
MR. ANDERSON: When you said I wanted to look

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at it to see if it confirmed or whether it was different, he's asking what did you find when you reviewed it.
A. What did you find? Yeah, more or less it is -- it is a confirmation of our experiences of the past 20 years.
Q. What is it about Dr. Iakovlev's report confirms your findings of the last 20 years?
A. To make it briefly, the presence of inflammation, the presence of scarring, the presence of nerves that are entrapped in -- in the scars.
Q. Is that all?
A. That's not all, but these are major points.
Q. Do you have -- did you review the opinion of Dr. Iakovlev with respect to his suggestions that polypropylene degrades in vivo?
A. Yes.
Q. And have you attempted to replicate the experiments that he conducted where he claims to have created a bark on the slides?
MR. ANDERSON: Objection as to misrepresenting what he said in his report, but go ahead.
A. I personally did not make my own studies to -- to see these barks or degradation, so...
Q. As of today, what is your recommendation for an

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alternative design for mesh used for the treatment of stress urinary incontinence?
MR. ANDERSON: Objection. We already went through this in 2013, 2012.
Q. Let me ask you this question: Has your opinion changed from the time that we spoke in 2013 about your recommendation for an alternative product for the treatment of stress urinary incontinence?
MR. ANDERSON: Okay. You can answer that.
A. I think it is -- it is outlined in the report where the problems are, where the high risks of the PROLENE is, and where the options for a safer alternative design is. And we can go through all these aspects in detail to -- to see where are the alternatives.
Q. Doctor, I'd like to do that but Mr. Anderson's not going to let me.
MR. ANDERSON: Okay, go ahead. Go ahead. It seems like you're close to the end. Go ahead.
Q. Let's turn to your report then, on Page 36. Are you on Page 36? Under safer alternative designs, one such safer alternative design would be a mesh product with less material, larger distance between the mesh fibers, and then you reference Ethicon's Ultrapro.
In prior depositions you've told me that

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Ultrapro was not an appropriate device for the treatment of stress urinary incontinence. Are you suggesting now that it is an appropriate device for the treatment of stress urinary incontinence?
MR. ANDERSON: Objection to the form of the question. Go ahead.
A. The Ultrapro in its present form, or with these huge pores with these material reduction, has of course advantages in comparison to the PROLENE material in regard to the tissue response. There has been a Turkish study clearly showing that it can be used as an alternative. However, I know --
Q. Alternative for what? I'm sorry.
A. For the PROLENE mesh.
Q. For stress urinary incontinence?
A. Yes, it was done, a Turkish study for treatment of stress urinary incontinence.
Q. Has that been in the last two years?
MR. ANDERSON: Well, let him finish his answer. You keep interrupting him and he was trying to answer the question.
MR. THOMAS: I apologize, Ben. I'm not trying to interrupt him at all.
MR. ANDERSON: You're not trying to, but you are. So go ahead.

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A. However, I know that Ultrapro has some disadvantages in regard to the structural stability, and therefore I wouldn't like to have this in my body.
Q. Okay. Is the Turkish study to which you just referred in the last two years?
A. I do not remember the date of the publication, whether it's before or within the past two years.
Q. Is it in your reliance materials?
MR. ANDERSON: It is.
Q. Thank you. Do you remember the first author on the study?
A. It was O., Ozark?
MR. ANDERSON: Let's look at the study. Let's not be guessing. Do you have the study?
MR. THOMAS: I don't.
Q. Let me see if I can go ahead on this.
Is your -- is it your opinion in your area of expertise that Ethicon's Ultrapro mesh is an appropriate safer alternative design for the treatment of stress urinary incontinence?
A. As I outlined, there are certain risks by the -- by the PROLENE that is the small pores, that is the huge amount of material and, of course, reduction of material making larger pores will reduce these risks.
Whether in the specific function of a sling the

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Ultrapro really over the time will work really better or whether it will create some new problems because of the structural deficits, I'm not able to predict now. I have concerns for both.
Q. And your concerns for the Ultrapro are what?
A. The concerns of the Ultrapro, one of the major concerns on the Ultrapro is that at really small forces the pores collapse. That means that the filaments are coming very close together, that you have an increased tendency for roping, or what the Weyhe group said, shrinkage, this deformation of a small textile in the construction of the Ultrapro, and that is -- that is the major concern. And that will lead to scar formation, that will increase the risk for chronic pain.
Q. And how do you answer those questions, whether the Ultrapro is sufficient for treatment of stress urinary incontinence?
A. Sufficient in regard to what are -- what is the textile structure that overcomes most of the risks, then Ultrapro is not the best candidate for this. But it is better than PROLENE.
Q. Do you know whether it is effective in the treatment of stress urinary incontinence, this PROLENE?
A. Effectiveness in the -- in the meaning whether it can work, as it was shown that it can work, as if you

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want to know whether it is as safe, then we have to admit that it is very difficult to -- to -- or we have to discuss the problem of safety assessment in detail.
Q. What kind of testing would be required to compare the use of the Ultrapro for the treatment of stress urinary incontinence compared to the PROLENE mesh for the treatment of stress urinary incontinence?
A. Which testing?
Q. Yes. What kind of testing would you do?
A. The testing I would do is as we did it with Ethicon starting in 1994. We have to make preclinical tests, we have to make an independent textile analysis, we have to look to tissue reactions looking at animal explants, at human explants, and we have to look to the results in registries, and in particularly to the failures, whether the failures can be avoided. And then we should get a good idea about the risks that are linked to the device.
Q. The other safer alternative design that you identify in your report is the PVDF material?
A. Yes.
Q. As you sit here today, are you aware of any PVDF sutures available for -- strike that. Are you aware of available -- Doctor, as you sit here today, are you aware of any PVDF meshes that are sold for the

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treatment of stress urinary incontinence in the United States?
A. I don't know.
Q. Okay. And with respect to the safer alternative design that you propose using PVDF, do you have a design in mind?
A. The design again has to consider the amount of the material; it has to consider the distance between the fibers; it has to consider the stability when applied to load; it has to consider the particle loss when trimming or cutting the material; it has to consider the local cell reaction to the polymer surface, and all of this together has to be considered and to realize a safe design.
Q. Does the DynaMesh PVDF mesh for the treatment of stress urinary incontinence meet your criteria for a safe and effective mesh for the treatment of stress urinary incontinence?
A. It meets several of these aspects, yes.
Q. What does it not meet?
A. I don't know whether it does not meet, but I don't have any data about, for example, particle loss.
Q. Okay. What other --
A. I didn't study it.
Q. What other than particle loss are data points

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that you don't have about the PVDF mesh that you'd need to have before it would be a safer alternative design?
MR. ANDERSON: Object to the form. Object to the way you asked that question. Go ahead. It misstates his testimony. Go ahead.
A. The advantages of this design is that it has a polymer that uses less inflammation, less scar. It has a textile construction that is -- that shows higher resistance to pore collapse, so it is more structural stable. It has borders that are not cut, but they are sealed by the textile manufacturing. So that is -- these are at least three, four advantages of this design.
Q. I understand your advantages. What you told me before, I believe, was that there were certain data points on issues that you've identified in your report for which you have not collected data. One was particle loss. Is there anything else that you would need to know before you would recommend the DynaMesh mesh to be marketed in the United States as a safer alternative design to TVT?
MR. ANDERSON: Object to the form of that question. Misstates his testimony. Go ahead.
A. Please, I have to -- can you read -- reread the sentence?

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Q. Let me go back a few.
MR. ANDERSON: I'm going to object because you keep saying --
MR. THOMAS: I understand what you're objecting to, Ben. I hear you. I'm trying to clean it up for you, all right?
Q. Okay. I asked you the question, does the DynaMesh PVDF mesh for the treatment of stress urinary incontinence meet your criteria for a safe and effective mesh for the treatment of stress urinary incontinence. Your answer was, it meets several of those aspects. Then I asked you, what does it not meet? I do not know whether it does not meet but I don't have any data about, for example, particle loss. What I'm interested in is what other criteria do you not have data for.
A. But then you asked another question.
MR. ANDERSON: But he's asking this one. Are there any other categories that you don't have data for? You said you don't have particle loss. Are there any other categories that you don't have data for is what he's asking.
A. I don't know data about the subsequent tearing force in the two directions. I don't know the stretching, stretching profile of this device at various loads. So it is not -- I didn't make a specific study

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to evaluate the use of the DynaMesh sling.
The point I was focused at was to demonstrate that the PROLENE sling, that there are alternatives possible, so that the properties of the PROLENE sling that not -- that is not necessary that the PROLENE sling is constructed.
There are alternatives, and one of these alternatives is realized with PVDF. There are others that took over some of the problems and found solutions that are less risky than realized in the PROLENE.
So if it is -- if these aspects are safer than PROLENE, if these are alternatives, yeah, these are alternatives and they will reduce -- these principles will reduce the risk that is realized by PROLENE.
Q. Let me go to Page 38 and Page 39 of your report. Are you there? Bottom of Page 38. "Based on these characteristics my studies comparing PVDF to polypropylene, Ethicon's internal documents and other scientific literature, as well as my background, training and experience over 30 years, it is my opinion, to a reasonable degree of medical and scientific certainty, that PVDF, in the appropriate design, is a safer alternative mesh material for treatment of stress urinary incontinence than Ethicon's TVT mesh."
What I want to know is, do you have the details

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of the appropriate design that's in that sentence that you can give me today?
A. I just can give you the principles for the appropriate design.
Q. Okay.
A. And these principles are no overengineering, material reduction, with the use of PVDF you have some more options, some more benefits, some less risks, larger pores. These are the principles. And the elasticity has to be adopted to -- to the needs for the demands of the tissues there.
Q. Okay. Are you finished?
A. Uh-hum.
Q. Is it fair for me to understand though you've not taken those principles and transferred those into a specific design of mesh using PVDF for the treatment of stress urinary incontinence in women?
MR. ANDERSON: Objection to the form. Go ahead.
A. It is -- it is correct that I was not responsible for the textile structure or for the design characteristics of the DynaMesh sling.
Q. Do you know of any risks that are present using a device for the treatment of stress urinary incontinence with PVDF?

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MR. ANDERSON: Objection. This is something that could have been covered or was covered at the last deposition. You're duplicating territory again.
A. As we discussed at the occasion of my presentations, complications can be done for several reasons, can develop for several reasons, and therefore of course can develop after use of a PVDF implant as well.
Q. In your last deposition you told me that we're not able to make specific conclusions that PVDF mesh by DynaMesh is better than the PROLENE polypropylene mesh. Is that still your testimony today?
A. Can you show me the specific --
Q. Page 32 of your deposition in 2013.
MR. ANDERSON: Okay. He's got it.
A. In regard or this statement has to be related to the -- to the -- if you are thinking of clinical studies showing the difference of one material over the other, we are not able to create clinical studies showing this. I'm -- in the moment we are not able to. So I hope the registries will show. If you include all our work, preclinical work and the analysis of the explants, it is clear, it is undoubted, if you look to the Ethicon documents, it is without any discussion that

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PVDF is superior as a material. That's it.
Q. Doctor, what's your current relationship with FEG?
A. It didn't change. We -- I've been working with the engineers from the FEG since our days with Ethicon in 1994, and I'm consulting them in -- in research questions. We had some funded research projects where the FEG is a partner for it. I'm, as you know, on some patents from the early 2000s.
Q. Have you had any new patents since your deposition in 2013?
A. No.
Q. I noticed that your mesh with iron in it has now come to market.
A. Yeah.
Q. Do you have any compensation arrangement with FEG where you're compensated for your work on that mesh project?
A. No.
Q. When we last had your deposition, you had no written agreement with FEG. Do you have a written agreement with FEG today?
A. No, no formal contract.
Q. At your last deposition you told me that you were paid approximately 25 to $30,000 a year from the

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FEG. How much money did you receive from FEG for the year 2013?
A. Thirty-five.
Q. Is that dollars or euros?
A. Euros.
Q. 35,000 euros?
A. Yeah.
Q. And how much money did you receive from FEG for 2014?
A. Similar.
Q. About 35,000 euros?
A. Yes.
Q. It's October of 2015. Have you received any money from FEG on a year-to-date basis?
A. Yes.
Q. How much did you get?
A. Because they are paying in the middle of the year.
Q. Okay. How much money did you receive from --
A. Similar.
Q. 35,000 euros?
A. Yes.
Q. Is that one payment?
A. It's one payment -- most of it is in the middle of the year, and every three months there it's 3,000

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euros.
Q. Okay. So how much money did you receive in the middle of 2015 from FEG in one payment?
A. 29,000.
Q. Okay. And then you received three other payments during the course of the year?
A. Two, April and July.
Q. Okay. And those were 3,000 euros apiece?
A. Yes.
Q. And this is in addition to FEG paying you to go to conferences to speak about their products?
MR. ANDERSON: Objection to the form of that.
A. The -- the compensation for the presentations are from Dahlhausen, it's not from the FEG, and what maybe is not included is some -- some travel expenses, directly travel expenses.
Q. And Dahlhausen is the distributor for FEG; is that correct?
A. Yeah.
Q. Do you have any written agreement with Dahlhausen?
A. No. Just for the one presentation and then this, yeah.
Q. The last time we were together we talked about a video presentation that you helped -- you and the FEG

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worked together on. Have you prepared any other video presentations for the FEG since your last deposition?
A. Not that I recall.
Q. Have you provided any assistance on the product literature for FEG for the products that they sell?
A. Not that I recall.
Q. What do you do with FEG in order to earn this money that you've been paid every year?
MR. ANDERSON: Objection.
A. So we are currently developing these visible meshes, we are currently working on elastic meshes, and we are currently preparing other projects where I provided the scientific background for the engineers to -- to design their textile testing to create the modifications that later on are tested or are used in the project plans. So you need someone who is an expert in this field to -- to develop your products, and these are engineers and I'm a surgeon. They are thinking that it is a good job that I make.
Q. I'm sure you earn your money.
Since your deposition in 2013, have you been involved in any studies with the FEG comparing PVDF mesh to polypropylene meshes?
A. I don't think so.
Q. Okay. You gave me two PowerPoint presentations

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where Dahlhausen caused you to go to different places to talk about mesh properties that we talked about. Since 2013, your last deposition, how many times have you done that for that Dahlhausen?
A. For Dahlhausen it was Berlin I was asked to; Ghent was FEG, Neukirch was FEG. So Dahlhausen, maybe one, maybe one other.
Q. Okay. How many for FEG -- let me strike that and let me ask a better question.
Since your last deposition in 2013, how many times have you made presentations sponsored by FEG about your materials, issues that you've discussed here today?
A. Sponsored by FEG? Two, three times.
Q. Okay. And you continued to appear on the master hernia program for FEG.
A. On the masterclass I -- I will go there this year, yeah.
Q. Okay. And that's in addition to these other presentations we discussed?
A. Yes.
Q. Any other presentations where you've spoken about the benefits of PVDF, other than those from Dahlhausen, from FEG or the master hernia program, since your last deposition?
A. Any other presentations?

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Q. Yes.
A. I was invited to -- to go to the Swedish Conference of Surgeons and to talk about the ideal mesh. I was invited to the World Hernia Meeting in Milano to talk about the visible mesh there. I was invited to some other conferences to talk about the ideal meshes, as you can see in my CV, where the presentations are named.
Q. And for the last conferences you just identified, who -- who paid your way to those conferences?
MR. ANDERSON: Which ones, the ideal meshes?
MR. THOMAS: The ones he just identified.
MR. ANDERSON: Well, he said, as you can see from my CV, the presentations are named. Are you talking about just the ideal mesh ones?
MR. THOMAS: He talked about a Swedish conference, he talked about Milan.
BY MR. THOMAS:
Q. Who paid you?
A. It was all invited -- I have been an invited speaker, and the organizer of the conference, they took over the costs.
Q. Okay.
A. They got their money from all the manufacturers

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and asked them all. But I -- I do not have any specific relationship to any of them.
Q. Okay. Are you working on any new mesh products in the pelvic floor for FEG?
A. Currently not.
Q. FEG still use polypropylene in some of its products?
A. I believe so.
Q. Have you ever told them to stop using polypropylene in their products?
MR. ANDERSON: Objection. You already asked these questions at his last deposition. He's not going to keep answering them.
Q. Since your last deposition in 2013, have you told FEG not to use polypropylene in its products?
A. I'm presenting the risks of polypropylene since 1889.
MR. ANDERSON: Really, 1889? You're an old guy.
A. 1989. Since then I permanently presented to the audience the disadvantages of polypropylene and the advantages of PVDF, and of course they know.
Q. Okay.
A. It is their decision and I'm not involved in their decision.

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Q. A simple answer to my question, please.
Since your last deposition in 2013, have you told FEG not to use polypropylene --
A. No.
Q. -- in its in products?
Since 2013, have you worked with Dr. Klosterhalfen at FEG?
A. The linkage, from FEG, no.
Q. Okay. Have you continued to work with Dr. Klosterhalfen since 2013?
A. Yes.
Q. And tell me about your work with Dr. Klosterhalfen since 2013.
A. We had discussions about this -- some -- how to realize a fluorescence microscopy -- microscopically -- fluorescence microscopical analysis for -- for a new project, and I asked him for advice.
Q. What does that mean?
MR. ANDERSON: Fluorescence microscopy?
MR. THOMAS: I don't know what fluorescence microscopy is.
MR. ANDERSON: Then ask it. Why don't you explain it.
A. We are still working on the characterization of the inflammatory infiltrate around polymer fiber, and

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therefore we need new procedures, new techniques, new markers to -- to proceed there. And I'm trying to get a project, and the funding for this, and I am very happy that I can ask him, as an experienced pathologist, to give me some -- some helpful information to this.
Q. Are you working on any studies currently with Dr. Klosterhalfen?
A. He is -- he is working or he's still analyzing the explants he collected at his institute, and from time to time he asked me to have a look to the data and to provide the statistical analysis there.
Q. At your last deposition we talked about the collection of hernia meshes that you're gathering at your facility. I believe you told me at that time that you were not collecting any explants from the pelvic floor. Have you begun to collect any explants from the pelvic floor?
A. No.
Q. Doctor, since your deposition in 2013, have you identified any studies which describe clinical risks from fraying or particle loss from TVT mesh?
A. I do not recall that I really found clinical studies dealing with this problem, but I increasingly get aware that clinical studies have too many limitations to address this problem.

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(Klinge Exhibit No. 15 was marked for identification.)
Q. Doctor, I'm going to hand you what's been marked as Deposition Exhibit No. 15, and ask if you recognize this document. It's titled, Comparing Different Types of Suburethral Slings Using Perineal Ultrasound.
A. Yes.
Q. And you are on this -- is this an abstract?
A. Yes.
Q. Where was this abstract published?
A. I don't know.
Q. And who were these other people that are on this?
A. I assume it has been a presentation at a conference.
Q. Who are the other people on this -- on this paper, Exhibit 15?
A. Dr. Najjari is a gynecologist in the University Hospital.
Q. Here in Aachen?
A. Here in Aachen.
And Maass has been the head of the department for gynecology in -- at the University Hospital in Aachen, but he left this year. And Kirschner-Hermanns

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has been a urologist at the University Hospital in Aachen. She's now head of a department at the University Hospital in Bonn.
Q. And what role did you have in this presentation?
A. I provided more or less the statistical analysis and gave some background information about textiles, meshes.
Q. And FEG funded this research? Do you see on the second page under disclosures?
A. Yeah, obviously. I don't know any details about it.
Q. Okay. And where was this presented?
A. So far I remember they -- they presented it at the IUGA in Spain some time ago. It should be possible to find it by the Internet by Google research.
MR. ANDERSON: Did you say I-U-G-A? It just didn't come out on the record. I wanted to make sure it came out.
A. Yes.
(Klinge Exhibit No. 16 was marked for identification.)
Q. Let me show you now what we've marked as Deposition Exhibit No. 16. Deposition Exhibit No. 16 is a research article by most of the same authors dated

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July of 2014, that appears to publish in BioMedical Research International further findings on the same research. Have you seen this paper before?
A. I've seen this, yeah. And I get lost.
MR. ANDERSON: Okay. Just answer his questions.
Q. Why do you get lost?
A. If you look to the authors.
Q. That's my point. What happened to you?
A. I don't know. I don't know.
Q. Okay. Do you have any understanding of why this was published without you?
A. No, no opinion to this.
Q. Okay. And the bottom line is the authors in Exhibit 16 used the data that you all gathered from Exhibit No. 15, and concluded that the differences noted in Exhibit No. 15 had no impact on the resulting state of continence for the people who were examined. Is that fair?
MR. ANDERSON: Objection to the form.
A. First of all, they gathered. I didn't gather any of these results, so that the data they collected.
Q. Okay.
A. And the conclusion there, it has no impact that is reasonable, because it is a very small sample size

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and it will be impossible to -- to find any significant relationship to the functional outcome. It shows that to some extent material matters, and this can be objectified by ultrasound.
Q. But the material did not matter in the clinical outcome as found by --
A. No.
Q. -- Exhibit 15.
A. No. That will be completely wrong to assume this. They could not find a positive relationship to the outcome. When you don't find any significant relationship, this means that the study protocol has some limits, that the cohort size has some limitations, that the follow-up time has some limitations. But it is not allowed to assume the opposite that it was proven in this study that there is no linkage to the clinical outcome. That would be completely wrong.
Q. Okay.
A. And this makes the limitations of these clinical trials to address this question.
Q. Was Exhibit 16 published without your knowledge?
A. I was not involved in -- in the publication of this manuscript.
Q. Did you know the result of the manuscript

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before it was published?
A. I did know the results of their comparison as it was presented in the abstract.
Q. Okay. The conclusions that are expressed in Exhibit No. 16 were presented at the IUGA meeting?
A. As I told you, the data, the data I know. What they measured, they know. Their conclusion here I don't know and I wouldn't agree to it, or you have to agree that you didn't find it, but I was not involved in this.
MR. THOMAS: Another quick break, please.
MR. ANDERSON: Okay.
(Recess from 12:52 until 12:57 p.m.)
BY MR. THOMAS:
Q. Doctor, thank you for allowing me to stand over you.
Looking at Exhibit 2, which is your report, it has some handwriting on it. Necessary or unnecessary risk. What does that mean?
A. That is one -- one of the major questions that this report is dealing with. Necessary or unnecessary risk of PROLENE, whether there is some information that it is a necessary risk.
Q. Okay. And do you have an opinion in that regard?
A. Yes.

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Q. What is that opinion?
A. The risks that we or that are identified by the PROLENE are unnecessary.
Q. Okay. And unnecessary because you think they can be removed by some alternative design?
MR. ANDERSON: Objection, asked and answered, not only at this deposition, but also at other depositions.
MR. THOMAS: Since 2013.
MR. ANDERSON: However, go ahead. Answer about safe alternatives of the design.
A. I'm sure that they can be resolved by alternatives, and that was the context of this report in detail.
Q. Okay. And that's the discussion we just had about the alternatives.
A. The amount of discussions, yeah.
Q. Follow-up study protocol, sample size, no complication, no difference. What does that mean?
A. In many clinical trials you will not see any significant difference in the complication rates. And this is very often misused as confirmation of safety. If you don't see a -- if you don't get a concern by a clinical study it was misused as saying it is safe.
In fact, it usually reflects the insufficient

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design of the study, a too small sample size, insufficient study protocol with various levels that are not good enough to detect the difference and a very short follow-up. So there are a lot of trials using 50 patients, 100 patients, looking for a short period of time for some vague readouts or outcome parameters. They will not see anything, no problems, and then they are presented to the audience as safe and no problem.
And I know that many manufacturers are really happy to present these data, but it has to be very clear. These studies are not, or shouldn't be used, it's dangerous to use them as a sign for safety.
Q. I'm sorry. What does this say?
A. Elephants and horses.
Q. Ah.
A. So I would have been very happy if you'd give me a -- now I'm really happy that you allow me to talk about it.
We have in 1994 one of our first things was the independent textile analysis of meshes. And, as you know, the PROLENE is considerably overengineered, so it is possible to use it for elephants or horses, as you see on some of my presentations that I took an image of my horse at that time.
So PROLENE would be maybe an alternative if you

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want to treat elephants and horses. And then I would have been very happy if you asked me whether it is possible to treat pelvic floor with PROLENE meshes in elephants and horses, and I would answer -- I would have answered you, not, not even in elephants and horses. The strength may be sufficient, but all the other disadvantages, small pores, frizzling, roping, all this is still a problem of the PROLENE and therefore the risk even for elephants and horses would be unacceptable and unnecessary.
Q. Risk benefit ratio important. What does that mean?
A. Yeah, it's always the critical thing when you discuss with a patient whether to use a material, whether to use a procedure, to define the risk benefit ratio. And the risk benefit ratio of the material, that is my -- my point.
Q. Okay. And in terms of the risks of the procedure though, independent of the material, that's out of your area of expertise, correct?
A. I will let others to -- to discuss this.
Q. Possible options to prove safety. Is that the CT scan, or what is that?
A. No, that is just to -- then you have to discuss the limitations of clinical trials.

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Q. Clinical trials, I'm sorry.
A. Clinical safety. You have no chance to do it. To prove superiority, that means that you want to create studies comparing two different materials.
Q. I see.
A. And that is even more impossible, even more impossible than just to prove the safety. So therefore comparing clinical trials are not --
MR. ANDERSON: Are not what?
A. -- effective.
MR. ANDERSON: There you go.
Q. Chronic foreign body reaction, no doubt experience. What does that mean?
A. Animals, human tissues, literature, Ethicon's documents, chronic foreign body. We shouldn't discuss about whether there is a foreign body reaction or not. There is.
Q. Well, even if we wanted to, Mr. Anderson's not going to let me, because we've talked about that a lot.
A. Yes; but you agree.
Q. Agree with what?
A. That it exists.
Q. Let's go to the next question, please.
MR. ANDERSON: Here we go. Let's stay to it.
Q. What's this next entry on your report?

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A. The weight is important. So the more material the more foreign body reaction and its effects. Material reduction improves tissue integration, its effect. More material is better. So if you don't believe in this, the contrast would be that more material is better.
Q. I see.
A. It is ridiculous. No one will say it and therefore we can all accept this.
Q. Well, didn't Cobb say this in his report when he's saying because of the problems he experienced with the lightweight mesh with large pores that he moved to a heavier weight mesh in order to have more structural stability to his pores? Doesn't he say that?
MR. ANDERSON: Objection.
A. You can reduce the amount of material to a point where the function is no longer guaranteed, yes.
Q. What's this entry down here mean? I can't read your writing.
A. One important point that has to be discussed is the hernia surgery and the PROLENE is a mesh intended to be incorporated as a flat mesh in a tension-free area.
So these are -- it's a hernia mesh. And when you -- when used to replace a ligament you have to consider mechanical strain and then you have pore

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collapse and then you have small pores.
And there are good Ethicon documents and they acknowledged the problem and talked about stress healing. So all this is in this report, as you see. It's just that I don't forget to mention some of the principles.
Q. Thank you.
In comparison to laser cut, what does that say?
A. Cut to other borders?
Q. Okay. Ten percent lost, 20 percent variation, increase in surface. Is that what that means?
A. Yes. There are documents clearly showing that 10 percent of the weight is lost by these particles, can go up to 10 percent in the mechanical cut devices. It's incredibly a high number.
Q. Go ahead.
A. And the second thing that would worry me or that worries me is that because of the cutting of small strides, of big huge flat mesh, you have a variation in bits of up to 20 percent, so that the -- it is a --
Q. A variation in what?
A. In width of the sling. So the sling can be 10 millimeters or 12 millimeters. It is not possible to make it more acute, according to the Ethicon documents, and it is clear because you are just -- it depends

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whether you cut in the -- directly in the line of the warp of that filament or a little bit right or left.
Q. Okay.
A. And therefore you have this huge variation, 20 percent variation of width, 10 percent material loss that is with a mechanical cut. And this is a risk, yeah, of course.
Q. Okay. Do you know of any studies or any papers that suggest how much of that 10 percent goes into people as opposed to being in the box or on the floor?
A. No, no.
Q. Okay. Evidence of possible levels to define what?
A. Whether a material is safe or not.
Q. Okay.
A. We don't have the option for clinical trials. We are waiting on registries. We have to build them up. We have the preclinical results giving a lot of warnings, yeah. So there are some risks for the PROLENE solutions for all issues. We can present them, that there are solutions for all, and therefore it's unnecessary and it is -- the Ethicon people in their documents, they are in full agreement with our -- with this statement, at least some of them.
Q. What does that say?

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A. This is -- this is a history of our collaboration with Ethicon and that we received 60 boxes with various materials, they are called CV, with a specific number. You certainly have all the material of it. We received more than -- more than 20 modifications from them.
Q. Modifications meaning different kinds of mesh?
A. Surface coatings, various pore size. We received even PVDF meshes from Ethicon at that time. So, yeah.
Q. On Page 9 you say textile forces. What is this?
A. Scar forces. That is what we already discussed, that you have to separate shrinkage forces in these two forces.
Q. And what's the purpose of this note at the bottom of Page 9? PROLENE hernia mesh.
A. Weight. It is the topic, weight, and our aim of our collaboration was to reduce it, and in fact Ultrapro is 30 percent less in comparison to PROLENE, and it has a completely different tissue reaction and everyone who feels it in his hands is clear.
Q. DynaMesh, Restorelle and Aries. Those are three other products that fit in here; is that right?
A. These are hernia meshes, these are pelvic floor

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-- devices from the pelvic floor.
Q. And what numbers --
MR. ANDERSON: Wait a minute. He's not through.
A. This is the -- the weight of this. This is an example that you can reduce the weight. This is an example that you can improve the border. DynaMesh we have discussed extensively.
Q. Since 2013 are you aware of any mesh used in the treatment of stress urinary incontinence that has a pore larger than that used in the Ethicon TVT device?
A. DynaMesh? At least DynaMesh sling has bigger pores when put to strain. So it has to be specified how to measure it and in which situation.
Q. That's the DynaMesh that's mentioned in Dr. Muehl's report?
A. Yes.
Q. Now, at rest, without measuring under strain, which pore size is larger, the DynaMesh or the TVT?
A. There is no -- as we extensively have discussed, there is no specific dimension or figure that can reflect the porosity.
Q. Okay.
A. In the report there is a textile porosity, there is an area of effective porosity, and there is a

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reduction after putting load to it.
Q. Do you have an opinion, if someone was to ask you which had a bigger pore size, without applying load to it, what would you say, DynaMesh or TVT?
A. We have to look to the --
Q. Do you know without looking?
A. That means the effective pores -- the percentage of effective pores without any -- any strain to it. I think it is maybe similar, almost close to 60 percent or so.
Q. Okay. Page 29. Nerve end scar. Is that what that says?
A. Yeah.
Q. Morphological substrate?
A. Morphologically substrate. When we have to tackle the problem with some of the patients with heavy weights, small-pore meshes such as PROLENE or Marlex, they experience chronic pain. We have to look into the explants. We have been very happy to identify that a possible reason, a morphological substrate for this clinical situation, is the entrapment of nerves, the deformation of the nerve endings in the neighborhood of the polymers. So the risk for pain likely is caused by this. And if you don't see any nerves the patient likely doesn't have pain.

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Q. Okay. Do you have any training in neuropathology?
A. No.
Q. Do you consider yourself an expert in the nerves in the pelvic floor?
A. I would consider me as an expert of nerves with textiles, in the neighborhood of textiles, wherever they are.
Q. Okay. And it doesn't matter the textile, whatever the textile there's a risk of the nerve being impacted by the textile, correct?
A. It depends from -- from the intensity of the scar and from the surface, from the amount of the material. If you have huge pores of five, four, millimeters, you hardly will see some nerves getting entrapped into the scar, and it is quite rare that these patients experience pain.
Q. In order, in your judgment, for these nerves that you've just identified to mediate pain to the patient, do they have to be trapped in the scar?
MR. ANDERSON: Object to the form.
A. I just would point out that when you see nerves entrapped in scar it is very likely the risk is very high for these patients that they experience pain. If you don't see nerves that are entrapped in scar, the

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risk is much, much lower.
Q. Are you able to distinguish between nerves that transmit pain and nerves that don't transmit pain?
A. No.
MR. THOMAS: That's all the questions I have, Doctor. Thank you.
MR. ANDERSON: Let's take a short break and let me go through my notes real quick.
(Recess from 2:17 p.m. until 2:30 p.m.)
CROSS-EXAMINATION
BY MR. ANDERSON:
Q. Dr. Klinge, I'm showing you what was marked as Exhibit 4 to your deposition that Mr. Thomas went over with you, this modified classification of surgical meshes. Do you remember some questions about this document?
A. Yes.
Q. Okay. One of the sections he asked you about was this one on Page 256.
MR. THOMAS: I don't mean to interrupt, but is that my highlighting?
MR. ANDERSON: It's my highlighting.
MR. THOMAS: Okay. Is this the original exhibit?
MR. ANDERSON: It's not the original, it's

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mine, the one you handed me.
MR. THOMAS: I apologize.
MR. ANDERSON: That's okay, okay.
Q. Mr. Thomas asked you this question: However, it is still open for further studies whether 500 microns is a reliable limit for histology and 1,000 microns for the calculation of the effective porosity or whether this should be modified. Did I read that correctly?
A. Yes.
Q. Can you please explain what you meant there and what this means by whether this 500 or the 1,000 should be modified? Please explain that.
A. The reason that we put this sentence into the text was that there was a discussion about or there were some facts indicating that you need maybe two millimeters or three millimeters as a minimum distance between the fibers to prevent this bridging. So it may be that these limits are too small, in particularly if you have some load on it. So the -- yeah.
Q. Were there any facts that would indicate to you that if it was going to be modified that it would go less than 1,000 microns between fibers?
A. No, I don't know any.
Q. Okay. Mr. Thomas also asked you about Exhibit 4, and he asked you whether or not any society

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in an official writing has adopted this. Do you remember that question that he asked you?
A. Yes.
Q. Do you need a society to adopt this classification for the science behind it to be valid?
A. No. These are facts. It doesn't depend from the meaning or the opinion of a society.
Q. You had mentioned that there were some different classifications for different things. For instance, you mentioned the Amid classification for your infection and your classification for higher risk for scarring or bridging fibrosis. Do you remember those questions?
A. Yeah.
Q. Okay. Have you seen any manufacturers in the last 10 years marketing their meshes by saying, our pores are large 75-micron pores that will prevent scar bridging between the fibers? Have you seen any manufacturer marketing their mesh devices saying that?
A. No.
Q. Have you seen any manufacturers at their conferences that they sponsor, including Ethicon, having speakers get up and talk about how 75 microns will prevent scarring and bridging and complications in patients?

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MR. THOMAS: Object to the form of the question. Go ahead.
Q. Have you seen any of those?
A. No. No one is relying on 75 microns for this purpose.
Q. Have you seen anything in the literature since Ethicon and your group created the lightweight large-pore meshes in 1998 indicating anyone disputing that greater than 1,000 microns between the fibers of an implanted surgical polypropylene mesh will prevent scar plating and bridging?
A. I'm not aware of any.
Q. You were asked a lot of questions about whether or not at some of the conferences that you speak whether or not FEG was one of the sponsors at those conferences. Do you remember those questions?
A. Yes.
Q. And you were asked some questions as to whether or not you had your expenses reimbursed or you got paid some per diem for speaking at those conferences by FEG. Do you remember those questions?
A. Yes.
Q. Does Ethicon sponsor conferences all around the world for surgical meshes?
A. Definitely, yes.

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Q. Does Ethicon pay its speakers and/or reimburse them for their expenses when they speak at those conferences?
A. Yes.
Q. When you spoke at the request of Ethicon numerous times, according to your CV, and they were a sponsor, were they sometimes sponsors at the conference?
A. Yes.
Q. Are they sometimes sponsors at the conferences at which you currently speak?
A. Yes.
Q. Did Ethicon reimburse you when you traveled and you spoke if they asked you to go speak there?
A. In former times they did it directly. Today they did it just by sponsoring the whole conference.
Q. Okay. You were asked some questions about Exhibit 12. That was the review article by Barski and Deng, do you remember this, where you were the academic editor?
A. Yes.
Q. Is the management of mesh complication, Doctor, SUI and POP repair, within your field of biomaterial science or hernia surgery?
A. No, it's out of my focus.
Q. Does anything in Exhibit 12 form the basis of

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your opinions in this case?
A. No.
Q. You were shown Exhibit 13, which is the new Cobb article. Do you remember being asked questions about this document?
A. Yes.
Q. Okay. This article under the background section indicates that they are going to present a consecutive series of elective retrorectus mesh repairs of an abdominal wall in an attempt to determine predictors of wound events and recurrence, and it mentions in this that it's going to deal with central mesh ruptures of complex incisional hernias. Is that what this article is about?
A. Yes.
Q. How does adapting different mesh design for central mesh ruptures of complex incisional hernias relate to pelvic floor meshes?
A. It's a completely different thing. The central mesh rupture within the abdominal wall is a consequence of the very high biomechanical forces in the abdominal wall that will not occur in the pelvic floor, and therefore the problem that is described in this setting with these large hernias cannot be applied to other fields in surgery.

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Q. What's the definition of the word "power" with regard to a study? What does that mean?
A. Statistical power usually means that if you don't see a difference that maybe there is still a difference and therefore you can, for these so-called beta error, you can call the sample size.
Q. What was the sample size here?
A. You have to calculate it in detail. But usually if you have an effect in 10 percent of the cases, you need more than 1,500 patients per group to have a sufficient statistically power of 80 percent to be sure that if you don't have a concern, if you don't have a problem, that there really is -- that there likely is no problem. So you need a huge cohort.
Q. Would 255 patients meet your definition of a huge cohort in this example?
A. Definitely not, and they mixed up several procedures, they mixed up several materials, so they formed several subgroups there. And, for example, if you -- if you just use five subgroups it is not 250 patients per group, but it's only 50 patients per group.
Q. Okay.
A. And this is in relation to the 1,500 you need. So it is not justified to -- to make the conclusions as the beta.

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Q. Okay. Mr. Thomas asked you a number of questions about whether or not Cobb and his four colleagues here, in changing their current practice, as he pointed out on Page 612, whether or not they had proven in this article that lightweight meshes have a larger risk of complications than other meshes, midweight meshes. Do you remember those questions?
A. Yes.
MR. THOMAS: Object to the form of the question.
Q. Okay. When they compared meshes about what they had been using to what they're using now, do you see anywhere in this article where they were using old construction six-mill PROLENE to treat their hernia patients?
A. No, they do not, and therefore they are in total agreement with Heniford who would refuse the use of heavyweight meshes and they preferred the midweight meshes.
Q. And when it says a midweight mesh on Page 612, what do they list for the weight of the midweight mesh?
A. Forty-five grams per square meter. But there is no -- no final definition what is midweight, it is just a description.
Q. Okay. But for our discussion let's just talk

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about the weight of in grams per meter squared. The midweight mesh that they characterize here was 45 grams per meter squared you said?
A. And that is less than half of the -- of the PROLENE mesh in this specific situation where you need a very strong repair.
Q. So did they say in this article, we don't want to use lightweight meshes, we'd rather use heavyweight, 105 gram per meter squared PROLENE? Do you see that anywhere in this article?
A. No, definitely not.
Q. What percentage of hernia surgeons in Germany, let's take for an example, still use old construction PROLENE or PROLENE of any construction for hernia repair?
A. PROLENE in every construction.
Q. Whatever construction PROLENE is available on the market today, how many --
A. PROLENE, PROLENE, not polypropylene.
Q. Correct, yeah.
A. The use of PROLENE is rare, probably less than 10 percent, for an incisional hernia.
Q. Does a discussion of central mesh rupture for complex incisional hernias relate to whether the TVT PROLENE causes increased risk in women?

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A. No, it's a completely different setting.
Q. Okay. Let's go to Exhibit 14. You were asked some questions on this Dirk Weyhe and William Cobb article. Do you remember some questions about this?
A. Yes.
Q. Okay. And this was the minipig hernia model. Do you remember that?
A. Yes.
Q. Is that a flat mesh or a mesh that gets put under tension like the TVT sling?
MR. THOMAS: Object to the form of the question.
Q. Does a TVT sling get put under tension when it's either placed by the physician or in vivo?
A. Yes.
Q. Okay. Were the meshes that were put into these minipigs in a hernia model, did they have forces placed on them like the TVT?
A. They were considered not to have forces.
Q. In fact, if you look at the abstract, under methods, were the meshes in this article, were they even meshes that are on the market?
A. None of it.
Q. Are those called experimental meshes that you use for research?

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A. Yes.
Q. On the second page of this article that Mr. Thomas showed you, if you look under the introduction, it says, "Nowadays it is well known that pore size is a key influencing factor of biocompatibility in terms of mesh integration, scar plate formation and chronic inflammation."
If by pore size we mean the distance between the fibers, do you agree with that statement?
A. Yes.
Q. Then it goes on to say, "A typical phenomenon of scar formation may cause the retraction of the mesh and it is proven in preclinical studies that small pores, less than one millimeter, induce a connective tissue scar plate which is described as the bridging effect by Klinge and colleagues." Do you agree with that statement?
A. Yeah, totally.
Q. And are you or any of your colleagues authors on this article that counsel pointed out to you?
A. No, unfortunately not.
Q. He also asked you a question about this sentence: "To our knowledge the correlation between elasticity, stability porosity of mesh constructions and shrinkage is not proven systematically up to now." Did

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I read that sentence correctly?
A. Yes.
Q. What do you understand that to mean, this systematically?
A. If you just ask whether it's proven, yes, it's proven. If it is investigated systematically so that we really have a good understanding about the relationship between elasticity, stretching, pore size and shrinkage, no, there is lacking sufficient studies that really deals with this problem systematically.
Q. Despite the fact that there may not be systematic clinical studies or safety studies in the literature, do you have an opinion as to whether or not elasticity, stability of porosity of mesh constructions and shrinkage will cause complications in patients?
MR. THOMAS: Object to the form of the question.
Q. Do you have an opinion?
A. Yes.
Q. And what is that opinion?
A. These are one of the basic reasons for these complications.
Q. And in this paper on Page 51, do these authors cite the work by you and Muehl in looking at effective porosity? First let's look at Reference 28.

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A. Twenty-eight.
Q. Or do they cite the work by you and Klosterhalfen?
A. They cite our proposal for classification.
Q. And that was the one that we looked at earlier? Does that have effective porosity and Muehl's work in the classifications?
A. Yes.
Q. Also reading from this article, Cobb and his fellow authors say, "In our series 89 to 100 percent of the large-pore meshes were well integrated at the edges, while 50 to almost 70 percent, 67 percent of the small-pore meshes were not." Did I read that correctly?
A. Yes.
Q. Do you have an opinion as to whether or not, if you have large-pore meshes that are well in -- strike that.
What does this demonstrate to you?
A. Though it's not clearly defined what they assume to be well-integrated, but it indicates that the large-pore meshes have a better tissue integration than the others.
Q. Let's go to their summary. Let me read the summary along with you. "A pore size greater than 1.8 millimeters," that's 1,800 microns, correct?

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A. Yeah.
Q. "Seems to have a better integration and higher biomechanical capacity. The mesh shrinkage is dependent on the implant's structural stability."
Do you agree with those two sentences?
A. Yeah.
Q. Are those opinions that you've outlined here today and in your report?
A. Yes. This is the publication from Bayon.
Q. Correct, Exhibit 14.
A. Uh-hum.
Q. Thank you.
Are you aware of any -- you were asked by counsel some questions about comparison of lightweight -- strike that.
You were asked some questions by Mr. Thomas about studies comparing shrinkage of smaller-pore meshes with larger-pore meshes. Do you remember those questions?
A. Yes.
Q. Are you aware of studies that compared larger-pore meshes and smaller-pore meshes to look at shrinkage?
A. I'm aware of studies looking at shrinkage by ultrasound, yeah.

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Q. Did you -- have you looked at explant studies in preclinical models to look at shrinkage of larger-pore meshes versus smaller-pore meshes?
A. Yes.
MR. THOMAS: Object to the form of the question.
Q. I'm sorry. You can answer.
A. Yes.
Q. Okay. Going back how long? Strike that.
When you worked with Ethicon, did you publish -- strike that.
In 1998, did you make any publications regarding shrinkage in smaller pore versus larger-pore meshes?
A. Yes. Shrinkage became an issue at one of the Suvretta conferences when Amid published for the first time what he's calling meshoma, and we tried to -- to study it in an animal experiment, and we published it, and we compared a heavyweight PROLENE mesh with lightweight, large-pore meshes in a dog study and published it and studied it extensively with the guys from Ethicon who came to Aachen at that time. So it was '98, I believe.
Q. In your studies with Professor Klosterhalfen and other colleagues that Mr. Thomas has asked you about

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regarding 1,000 explanted meshes, the 600-plus explanted meshes and any other of your work, have you noticed a correlation between smaller-pore meshes and shrinkage?
MR. THOMAS: Object to the form of the question.
A. Yes.
Q. Okay. And what is that correlation?
MR. THOMAS: Same objection.
A. The shrinkage is more extensive the more scar you have.
Q. With -- with -- strike that. Let me go back.
For your explant studies that you've done with Professor Klosterhalfen and others, the ones that have been presented to you here today by Mr. Thomas, have there been a correlation between the distance between the polypropylene fibers of those explants at less than 1,000 microns and shrinkage?
MR. THOMAS: Object to the form of the question.
A. If you have a lot of shrinkage or better say scar contraction there, you usually -- or you have a smaller distance between the fibers, that is something you see at the explants, but this is something you can feel during any revision operation when you're feeling, when you're getting this material and the tissue in your

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hands.
Q. In all of the materials that you've reviewed from the internal Ethicon documents, all of the depositions of Ethicon employees, and any literature published by Ethicon or its key opinion leaders, did you ever see that Ethicon tested the structural stability of the PROLENE used in TVT to see what the resistance of pore collapse under load would be?
MR. THOMAS: Object to the form of the question.
Q. As it would be used as a sling.
MR. THOMAS: Same objection.
Q. Have you seen any studies where they actually study that?
A. There are documents where they -- they put the slings to -- to forces.
Q. Did you ever see where they determined what the structural stability would be necessary for the slings and how to adapt the mesh in the TVT to respond to those forces?
MR. THOMAS: Object to the form of the question.
A. I didn't see any study where they are dealing with the problem to overcome it, but just to demonstrate the problems there are several images showing that there

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is a problem.
Q. Do you have an opinion -- well, strike that. Let me go back.
You had some questions by Mr. Thomas about safer alternative designs of slings versus the TVT PROLENE. Do you have an opinion as to whether or not the DynaMesh sling made of PVF would be safer in women than the TVT sling with PROLENE in it?
A. Yes.
MR. THOMAS: Object to the form of the question.
Q. What is that opinion?
A. That the DynaMesh design is safer, because it considers the principles and avoids the high risk problems of the PROLENE mesh.
Q. You were asked some questions about whether or not you had done this video presentation for FEG, you and Professor Klosterhalfen. Do you remember those questions?
A. Yes.
Q. Did Ethicon ever ask you to be video'd regarding the lightweight large-pore meshes?
A. Yes.
Q. Did they do that?
A. Yes, they asked for a video session where I was

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asked to demonstrate the entire story of the development of the first lightweight, large-pore hernia mesh, the Vypro. So I was asked to -- to tell how they -- how we worked together over the years. And this was a video that was shown at -- at the conferences where the industry where Ethicon has a stand. There it was running on a monitor all day or all time around, so permanently you could see that the story --
Q. You mean on a constant feed?
A. On a constant feed.
Q. Okay.
A. It was shown. And, yeah.
Q. So Mr. Thomas asked you some questions about the pore size, and I know you've had some discussions about what do you mean by pore size. But let's just go back to his questions.
He asked you whether or not the pore size of DynaMesh and the TVT slings, he asked you about pore size out of the box, not in use, he said out of the box.
Do you have an opinion as to whether or not the pore size of any mesh, as it comes out of the box, is important to a patient?
MR. THOMAS: Object to the form of the question.
A. It is -- it will create or it is not important

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for the patient because it has to be seen in relation to the functional needs for this mesh. And if you just would -- would think that the text or that the distance between the fibers when putting out of the box is sufficient, then it would put the patient to a serious risk, particularly if you place the device in a position where you applied some force to it.
Q. Let me see if I can make this more simple. Does the -- does the distance of the -- distance between the fibers for mesh out of the box have any relationship to patient safety once it's in the body?
MR. THOMAS: Object to the form of the question.
A. No. The most important thing is what happens in the tissue, the distance of the fibers in the tissue.
Q. Okay. Mr. Thomas pulled out your deposition from November 14, 2013, and he showed you one question and answer from Page 32 and 33. Do you remember that?
A. Yes.
Q. And do you recall this series of questioning? I want to take you back to Page 26. Question: What studies in the last year have you published or will be published? And then your answer: Let me start from the last because it's more easy to recollect. Did I read that correctly?

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A. Yes.
Q. And then do you go on, on Page 26, 27, 28, 29, 30, 31 and 32 talking about those studies that you were doing with Professor Klosterhalfen?
A. Yes.
Q. And then the question on Page 32: Does this study analyze the extent to which one design of a mesh may be better than another? And you said: No, it is not possible because of the variation by intent, the variation is too big.
Was that answer and that question in your mind related to these one, two, three, four, five, six pages of this one study?
A. Yes, in the text, this study.
Q. And then when he says, are you able to conclude from the research that you've done whether PVDF or polypropylene are better meshes for the issues that you were studying, was that question in your mind related to the six pages before it about those studies?
MR. THOMAS: Object to the form of the question.
A. Definitely, yeah.
Q. Okay. So when you said, as I told you, we are not able to make specific conclusions that one is better than the other, what did that relate to?

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MR. THOMAS: Object to the form of the question.
A. That was related to this specific study where we looked to the cell reaction in the neighborhood to polypropylene and PVDF.
Q. Thank you.
MR. ANDERSON: No further questions, Counsel.
REDIRECT EXAMINATION
BY MR. THOMAS:
Q. Let's go to Page 464 of your deposition on November 15th, 2013.
MR. ANDERSON: Four what?
MR. THOMAS: 464.
MR. ANDERSON: 464.
Q. Line 8. Other than that study you just described, which is an exhibit that we've talked about today, it's in the gerry abstract, "Are you aware of any clinical studies that compare the use of PVDF to the use of polypropylene in any application to determine which is better?" Answer: "No, I don't recall any clinical study." Is that correct?
A. That is correct.
Q. And is that answer true still today?
A. Yeah.
Q. It is true today?

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A. There are sufficient number of clinical studies showing that it is -- that PVF is used and can be used, but comparative clinical studies, there is not one in the world which is sufficient.
Q. Okay.
A. So there is --
Q. This doesn't ask --
MR. ANDERSON: Hold on. Let him finish. You can duck your head if you want, but when a man's talking you can't --
MR. THOMAS: I'm doing the best I can. Don't comment on my mannerisms, please.
MR. ANDERSON: But you look disgusted with me.
MR. THOMAS: I'm not disgusted with you, I'm trying to get through the day. Just let him go ahead.
MR. ANDERSON: You can answer your question.
A. So there is no option for us to do a comparative clinical study with sufficient statistically power.
Q. Are you finished?
A. Yes.
Q. Thank you.
The question that was asked back then, and what I've tried to ask today was, are there any clinical

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studies that compare the use of PVDF to the use of polypropylene in any application to determine which is better? No, I don't recall any clinical study. Not about power, not about sufficiency, not what studies in your judgment are not adequate to answer the question. Are there any that you've reviewed comparing the use of PVDF to the use of polypropylene in any application to determine which is better?
MR. ANDERSON: Objection to the form of that question. Go ahead.
A. No, I don't recall any.
Q. Thank you.
A. And it is not possible.
MR. THOMAS: Okay. Thank you. That's all.
MR. ANDERSON: That's all your questions?
MR. THOMAS: Yeah.
RECROSS-EXAMINATION
BY MR. ANDERSON:
Q. Doctor, is it possible to do a clinical study comparing any mesh design in order to determine the safety, not just PVDF and polypropylene, any clinical study by any manufacturer or any scientist?
MR. THOMAS: Object to the form of the question.
A. I cannot imagine how this can be realized

sufficiently.
Q. And those were the reasons you've explained here today as to why you can't do a clinical study for safety comparing meshes?
A. Yes, safety, yes.
MR. ANDERSON: That's all we've got.
MR. THOMAS: Thank you, Doctor. Nice to see you again.
(Signature having been waived, the deposition of DR. UWE KLINGE was concluded at 3:04 p.m.)

CERTIFICATE

I, TRINA B. WELLSLAGER, Registered Professional Reporter and Notary Public, do hereby certify that, pursuant to notice, the deposition of DR. UWE KLING was duly taken on 10/5/15 at 10:07 a.m. before me.
The said DR. UWE KLINGE was duly sworn by me according to law to tell the truth, the whole truth and nothing but the truth and thereupon did testify as set forth in the above transcript of testimony. The testimony was taken down stenographically by me. I do further certify that the above deposition is full, complete, and a true record of all the testimony given by the said witness.

_____
TRINA B. WELLSLAGER, RPR

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LAWYER'S NOTES

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